UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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FEDERAL TRADE COMMISSION, STATE OF NEW YORK, STATE OF CALIFORNIA, STATE OF OHIO, COMMONWEALTH OF PENNSYLVANIA, STATE OF ILLINOIS, STATE OF NORTH CAROLINA, and COMMONWEALTH OF VIRGINIA,

Plaintiffs,

v. 20 CV 706 (DLC)

MARTIN SHKRELI, et al.,

Defendants.

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New York, N.Y.
December 14, 2021
9:30 a.m.

Before:

HON. DENISE COTE,
District Judge

APPEARANCES

FEDERAL TRADE COMMISSION
BY: MARKUS H. MEIER
MARIN HANEBERG
BRADLEY S. ALBERT
LAUREN PEAY
NEAL PERLMAN
LEAH HUBINGER

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BY: ELINOR R. HOFFMANN
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DUANE MORRIS LLP
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BY: CHRISTOPHER H. CASEY
JEFFREY S. POLLACK
ANDREW J. RUDOWITZ
SARAH FEHM STEWART
SEAN McCONNELL
J. MANLY PARKS

(Case called)

MR. MEIER: I am Markus Meier on behalf of the Federal Trade Commission.

MS. HOFFMAN: Elinor Hoffman on behalf of New York State and the state plaintiffs.

MR. ALBERT: Brad Albert on behalf of the Federal Trade Commission.

MR. PERLMAN: Neal Perlman on behalf of the Federal Trade Commission. With me is our paralegal, Stephanie Guy.

MR. CASEY: Good morning, your Honor, Christopher Casey with the law firm of Duane Morris on behalf of the defendant, Martin Shkreli.

MR. POLLACK: Good morning, your Honor, Jeff Pollack, the law firm of Duane Morris, on behalf of the defendant, Martin Shkreli.

MR. RUDOWITZ: Good morning, your Honor, A.J. Rudowitz from the law firm of Duane Morris on behalf of Martin Shkreli.

MS. STEWART: Good morning, your Honor, Sarah Fehm Stewart from the law firm of Duane Morris for the defendant Martin Shkreli.

MR. PARKS: Good morning, Manley Parks on behalf of the defendant Martin Shkreli.

MR. FIELDS: Good morning, your Honor, Justin Fields on behalf of defendant Martin Shkreli.

THE COURT: Mr. Fields, are you with Duane Morris as well?

MR. FIELDS: I am.

THE COURT: Thank you so much.

Welcome, everyone. Excuse me just one second.

MR. POLLACK: Your Honor.

THE COURT: Excuse me just one second.

Sorry, counsel. This is Mr. Pollack?

MR. POLLACK: That's right, your Honor. Just a point of clarification so there is no confusion. Mr. Fields is our trial technician. He's not an attorney. But he is with our firm.

THE COURT: Thank you so much. I appreciate that.

Let me just welcome everyone as we begin this trial, which is obviously very important to the government plaintiffs and very important to the defendant and, of course, to the public because it involves the enforcement of our antitrust laws. I want to thank everyone for working so hard to be well prepared for today's trial.

I want to remind everyone of our protocol because of the COVID pandemic. This courtroom has been tested. Its ventilation systems have been tested. There is a complete air exchange every ten minutes, if not more frequently.

Everyone must wear a mask at all times with the following exceptions: When I'm speaking I do not need to wear

a mask. When an attorney is examining from the podium, the attorney does not need to wear a mask. When the witness is seated in the witness seat, they do not need to wear a mask.

I am going to ask everyone in the well of the courtroom to make sure that my law clerks or Mr. Whertvine are notified of your vaccination status. I won't be putting that on the public record, but we want to know whether anyone in the well of the courtroom is not fully vaccinated.

Those seated either in the jury box or outside in the gallery of the courtroom must be seated six feet apart if you are not fully vaccinated, and three feet apart from another person if you are.

So those are the rules we will follow.

We are keeping time at this trial. I'm keeping time unless the parties have agreed on a different neutral timekeeper.

Mr. Meier, have the parties agreed on a different neutral timekeeper?

MR. MEIER: No, your Honor. We are fine with your Honor taking on that task. Thank you very much.

THE COURT: Thank you.

I am going to ask my law clerks to back me up, so you will have more protective hands on this task than just mine. At the end of each day I will try to give you notice of where we stand.

I was going to begin today by dealing with the remaining two requests for sealing of documents or the courtroom by third parties. Let me turn first to RL Fine. I don't have a direct application from RL Fine. Instead, I had a notification from defense counsel of December 6, which attached an e-mail, and that e-mail from RL Fine refers to extreme confidentiality. That's not sufficient for me to understand what its risks are here.

I made a number of findings yesterday that declined to seal or redact documents in which various parties were communicating with RL Fine. So unless the parties have some particular issue to bring to my attention with respect to RL Fine, I do not have a basis from which to order the sealing of any exhibit, in whole or in part, or the closure of any courtroom in connection with RL Fine testimony.

Not hearing anything from counsel, I turn to the last remaining application. It is from a third party, Medisca, and counsel for Medisca provided me a written description of its request on December 6.

It is a company, as I understand it, that supplied compounding pharmacies with the API of interest here and also was the source of the pyrimethamine that was used in a clinical trial conducted by a physician. Counsel did not appear yesterday to further explain this request and the principal point of the request is, as I understand it, that Medisca does

not want its source for the API to be publicly disclosed. Depending on what that source is and to be consistent with the rulings I made yesterday, the source will not be publicly disclosed unless it was one of two companies.

So, Mr. Meier, was the source one of two companies that will be publicly disclosed on this record, as far as you know?

MR. MEIER: I actually do not know that, your Honor.

THE COURT: I'll let counsel figure this out during a break and further advise me.

I take it this morning there will be no evidence offered with respect to the Medisca issues. Am I right, Mr. Meier?

MR. MEIER: I do not believe that the Medisca issues will come up today, your Honor.

THE COURT: Am I right, Mr. Casey?

MR. CASEY: That's my understanding, your Honor.

THE COURT: Thank you.

Mr. Meier, do the plaintiffs wish to offer an opening statement?

MR. MEIER: Your Honor, if I may, we do have a couple of administrative matters that we would like to take up, if that's possible.

THE COURT: Certainly.

MR. MEIER: We will not be doing an opening statement.

THE COURT: Yes.

MR. MEIER: Your Honor, we have an agreement with defendants on a first list of exhibits to be admitted. We had exchanged these back and forth with the defendants over the last weekend, last couple of days. I'd like to move in what we labeled as Government Exhibit 9001, which is a first tranche of exhibits to be admitted.

THE COURT: Do you have a copy of that document?

MR. MEIER: Yes, I do, your Honor.

THE COURT: If you could hand it to my law clerk, please.

MR. MEIER: Thank you, your Honor.

THE COURT: Counsel, where it's convenient, and this wouldn't be true for bulky exhibits, but where it's convenient, if you could hand up at least two copies of the document, one for me and, if possible, even three copies. I have two law clerks with me at this trial. Thank you so much.

Is there any objection to the admission of Government Exhibit 9001 and the documents listed on it?

MR. RUDOWITZ: Your Honor, we have no objection pursuant to the Court's guidance on the admission of GX-9001 and the exhibits therein.

THE COURT: 9001 and the exhibits listed therein are received.

(Government Exhibit 9001 received in evidence)

THE COURT: Next.

MR. MEIER: The next item, your Honor, is we have the deposition designations of a witness named Courtney Johnson from Cardinal. It's marked as Government Exhibit 9051. I have two copies to hand up and one for the defendants. Again, we have discussed this over the course of the last few days, and I believe this comes in without objection. I'll let the defendants speak for themselves.

We will bring three copies in the future for the Court. Sorry, your Honor.

THE COURT: Thank you so much.

This is a document describing actually the deposition of Patel.

MR. MEIER: I'm sorry. My file got mixed up. I apologize, your Honor. Let me start that over again.

THE COURT: I now have another document, GX-9051, which describes the deposition offer for Courtney Johnson of Cardinal.

How does 9051 relate to what was given to me in the white binders?

MR. MEIER: Your Honor, what we did is, with respect to Ms. Johnson, there are no changes, as I understand it. When I give you the one for Mr. Patel, we will tell you exactly what's the difference on the first page. So with Ms. Johnson there are no differences.

Your Honor, by the way, this is also the designations from both defendants and plaintiffs.

THE COURT: The agreement between the parties is one party's designations are in yellow and another in blue. Who is in yellow?

MR. MEIER: There is a key, a legend at the top of each page. The yellow is the FTC's designations, the orangish color is the FTC's counter designations, the bluish and the greenish colors are defendant's designations, and defendant's counters, and there is a legend at the bottom of each page.

THE COURT: Very helpful. So well organized. Thank you very much. Great assistance to the Court.

Of course, with the original offer of deposition excerpts, I had the summary pages, one for the plaintiffs and one for the defendant, and those same pages apply.

MR. MEIER: Yes, your Honor. Going forward, should we submit those also?

THE COURT: No need. If I have them, I know where they are. Thank you.

Any objection to the receipt of Exhibit 9051?

MR. POLLACK: No, your Honor. We consent to the admission of both parties' designations.

THE COURT: That's Mr. Pollack?

MR. POLLACK: I apologize, your Honor. Yes. Jeff Pollack.

THE COURT: 9051 is received.

(Government Exhibit 9051 received in evidence)

MR. MEIER: The next one we have, your Honor, I'm sorry I got them out of order, is 9050, Government Exhibit. It is the deposition designations revised for witness named Ravi Patel from a company called Espee. This one does have some changes from the original and it is described on the cover. I can come up.

THE COURT: Any objection to the receipt of Exhibit 9050?

MR. POLLACK: No objection to both sides' designations coming in as highlighted, your Honor.

THE COURT: That's Mr. Pollack speaking?

MR. POLLACK: Yes. I will get that right eventually, your Honor.

THE COURT: Again, this is very clearly explained on the front page, the difference with the original offer and what is now being actually offered at trial, and Exhibit 9050 is received.

(Government Exhibit 9050 received in evidence)

MR. MEIER: The last one, your Honor, is also deposition designations that have been revised. It's the deposition of Jacob Mathew. Mr. Mathew is with the company RL Fine. The exhibit number is Government Exhibit 9052.

With this one, your Honor, we do have a dispute with

the defendants, and we were hoping that we could get guidance from the Court this morning.

That will be handled by my colleague, Mr. Perlman. Mr. Perlman has additional copies of the exhibit.

MR. PERLMAN: Good morning, your Honor. May I approach to pass up these copies of the exhibit?

THE COURT: Yes.

I am going to interrupt. Mr. Meier, you weren't here yesterday afternoon for the entirety. I wanted to tell you your colleague handled the issues admirably.

MR. MEIER: Thank you very much. Appreciate that.

MR. PERLMAN: Your Honor, I have tabbed he these three copies of the transcripts where the disputes lie.

THE COURT: You can move to the podium. That's an option for counsel, all counsel. Feel free if it's more convenient for you. Either that, or really keep your voice up.

Mr. Perlman.

MR. PERLMAN: Good morning, your Honor. Again, this is Neal Perlman for the FTC. Both plaintiffs and defendants are seeking to admit portions of the deposition transcript of Mr. Mathew.

As my colleague, Mr. Meier, said, Mr. Mathew is the chairman of RL Fine, which is, as your Honor knows, one of the API suppliers at issue in this case. The plaintiffs and defendants took this deposition pursuant to the Hague

Convention.

The plaintiffs at this point maintain objections to two different passages of the transcript, which I have tabbed. The first one is on page 8 at the very top. It's question 13. And the next, which is related, is at the top of page 12.

The issue here, your Honor, is that defendants are seeking to admit Mr. Matthews' testimony, that it is easy to make pyrimethamine API and for that reason there must be 20, 15, 10 other API suppliers in India that can make pyrimethamine API.

But in his answers to those questions, he disclaims any foundation for being able to provide that information. For example, if we turn to the question on the top of page 8, that's, again, question 13. The local commissioner in India asks whether there are any other companies that have the ability to make pyrimethamine API and Mr. Mathew says that he thinks it's seventh grade chemistry, but says he's not a technical person.

And there is a similar exchange at the top of page 12 between plaintiff's local counsel, Nishant Joshi and Mr. Mathew. Mr. Joshi asked what the basis was for Mr. Matthews' assertion that it was an easy product to make and there were many companies that could make pyrimethamine API. Again, Mr. Matthews says, I'm not a chemical industry person. I'm a financial services person. There must be ten or 15

different companies.

We respectfully submit that Mr. Matthews doesn't have the foundation to provide these answers, and there is nowhere else in this transcript where he does mention any foundation for these statements.

THE COURT: Mr. Casey.

I'm sorry, Mr. Pollack.

MR. POLLACK: No problem. You didn't know that I would be the one speaking, your Honor.

Your Honor, to begin, this is the first time plaintiffs are raising an issue with number 13 on page 8. In my correspondence with plaintiff's counsel from the last several days, the only issue raised had to do with page 12. But I'll address page 8 as well since it's being raised today.

The question was, are there other companies that have the ability or --

THE COURT: Sir, whenever -- counsel, this applies to everyone. When anyone is reading from a document, they must slow down and speak up if they would like the court reporter to be able to capture what you are saying.

MR. POLLACK: Thank you for that good advice, your Honor.

THE COURT: Thank you.

MR. POLLACK: Number 13. Are there other companies that have the ability or you believe have the potential to

develop ability to manufacture pyrimethamine API. The objection lodged is that of speculation. The question is asking, what does the witness know? He provides a response.

My argument would be the same thing for the testimony at page 12. Any idea what was the source of that information. In other words, what do you know. And he gives a response.

So the form of the question is proper and the response is given. There should be no objection to that testimony.

THE COURT: The objection is sustained. The testimony is stricken.

Next.

MR. MEIER: That is all the administrative matters that the FTC has, your Honor. We would be prepared to call the first witness, unless the defendants have anything they need to raise.

THE COURT: You may call your first witness.

MR. MEIER: Thank you, your Honor.

The government calls as its first witness Dr. Pelliccione. I will be doing the examination, your Honor.

THE COURT: Dr. Pelliccione, if you could please come up here and take the witness stand. If you would remain standing, please.

NICHOLAS PELLICCIONE,

called as a witness by the Plaintiffs,

having been duly sworn, testified as follows:

THE COURT: Counsel.

MR. MEIER: Thank you, your Honor.

Just a quick administrative question. When a counsel is up here at the lecturn, am I permitted to go back to the counsel table if I need to without always asking for permission? I hope not to have it happen very often.

THE COURT: You don't need to ask permission to move around the courtroom, including to show a document to the witness. We are going to try to keep the record as spare as possible. I am afraid you are going to have to put your mask back on.

MR. MEIER: Correct. Thank you, your Honor.

Dr. Pelliccione is a witness for whom defendants have submitted an affidavit or a declaration, so I think Mr. Casey has copies?

MR. CASEY: Yes, your Honor. May I approach the witness?

THE COURT: Certainly.

If you could, Mr. Casey, identify the exhibit number that you are giving the witness so the record is clear.

MR. CASEY: Yes, your Honor. The exhibit number is DX539.

THE COURT: Thank you.

MR. CASEY: Dr. Pelliccione, I'm showing you what's been marked as DX539. Did you have a chance to look at DX-539,

Dr. Pelliccione?

THE WITNESS: I have looked at it previously, yes.

MR. CASEY: You recognize it?

THE WITNESS: Yes, I do.

MR. CASEY: What is DX-539?

THE WITNESS: It's the trial testimony that I provided.

MR. CASEY: Your Honor, pursuant to the Court's procedures, I understood that the Court would like to ask questions of the witness at this time.

THE COURT: Thank you very much.

Dr. Pelliccione, if we go to the last page of the document, page 11, did you authorize the attachment of your signature at that page?

THE WITNESS: Yes, I did, your Honor.

THE COURT: Did you do that after you had read the entire exhibit with care?

THE WITNESS: Yes, I did.

THE COURT: Do you swear to the truth of its contents?

THE WITNESS: Yes, I do.

THE COURT: Thank you.

Any objection to the receipt of DX-539?

MR. MEIER: Yes, your Honor. The government has two objections to DX-539 that we had raised previously with the defendants.

The first one, your Honor, would be paragraph 24 at page 6. If I may read, for the record, the part that we object to, your Honor. This is paragraph 24 which starts on page 5. But the portion we object to carries over into page 6. It begins with the sentence, at the time we entered into the supply. It's the second line at the top of page 6, your Honor. It says: At the time we entered into the supply agreement and now, I understood that it is common for companies to include exclusivity as a standard term in an API supply agreement.

I want to read the next paragraph that we also have an objection to because the objection is the same for both paragraphs.

The next one is paragraph 25, the very next paragraph, your Honor. It's also on page 6. It's the clause that starts in the middle of that paragraph that begins with: Again, I understand. So it says, your Honor: Again, I understand that such provisions are common in API supply agreements.

We believe the sentence that I read in paragraph 24 and the clause that I read in paragraph 25 should be stricken.

The reason, your Honor, is both are examples of improper lay opinion testimony in violation of Federal Rule of Evidence 701. There is no foundation that Mr. Pelliccione knows what is common for companies in the pharmaceutical industry. He hasn't conducted a survey, nor does he cite to any authoritative source. And we believe this testimony is

precisely of the type of technical or other specialized knowledge within the scope of Rule 702 and thus requires expert testimony, not lay opinion testimony, your Honor.

THE COURT: Mr. Casey.

MR. CASEY: Yes, your Honor. Thank you. Christopher Casey on behalf of Mr. Shkreli.

Your Honor, these statements that the plaintiffs have objected to simply reflect the witness' understanding based on his long experience in the pharmaceutical industry. As his affidavit indicates, he spent 35 years in this industry.

And the Court I'm sure is well familiar with the standards under Rule 701. The standards are that the opinion be rationally based on the witness' perception. These statements are indeed rationally based on Dr. Pelliccione's perception based on his knowledge in the industry.

Second, helpful clearly understanding the witness' testimony or determining a fact at issue. This is, we would submit, very helpful to the Court in determining whether these types of provisions are common in the industry.

Third, that it is not based on scientific technical or other specialized knowledge within the scope of Rule 702.

I would commend to the Court on that part of the test several cases from the Second Circuit. The first is *United States v. Dawkins*. That's at 999 F.3d 767 (2d Cir. 2021), at page 793 of that opinion. The Second Circuit affirmed the

district court's decision to allow witnesses who are part of a conversation regarding the industry of college basketball to testify about their understanding of jargon used during a conversation, and the Court pointed to the witness' long experience in the industry as being a significant factor.

I'd also point the Court to two other Second Circuit cases: *United States v. Rigas*, 490 F.3d 208 at page 224 (2d Cir. 2007); *United States v. Yannotti*, 541 F.3d 112, 125-126 (2d Cir. 2008). This kind of a statement, his understanding of what is common in the industry, does not depend on his knowledge of any specialized scientific training. It is rather a product of his long experience in the industry. We submit, your Honor, that this is proper lay testimony.

THE COURT: Objection is overruled. The testimony will be received.

Examination.

MR. MEIER: Thank you, your Honor.

DIRECT EXAMINATION

BY MR. MEIER:

Q. Good morning. Dr. Pelliccione.

A. Good morning.

Q. I believe you have already introduced yourself, but could you go ahead and state your full name.

A. Nicholas Pelliccione.

Q. I believe we have already spelled that for the court

reporter.

Dr. Pelliccione --

THE COURT: Doctor, if you could move that mic, move it up. It moves. Put it under your chin. Keep your voice up. Thanks.

Q. Dr. Pelliccione, we have never met before, but you have met some of my FTC colleagues at your investigational hearing in September of 2019 and your deposition about a year ago.

My name is Markus Meier. I work at the Federal Trade Commission. Is there anything that might affect your ability to give truthful complete testimony today?

A. No.

MR. MEIER: Your Honor, at this time I'd like to just introduce Stephanie Guy, who is sitting at counsel table. Ms. Guy will be assisting me. Hopefully, the Trial Director technology is working properly, and we will be able to put up exhibits that you will be able to see at that screen, Dr. Pelliccione.

Q. Dr. Pelliccione, you currently work at Vyera Pharmaceuticals LLC, correct?

A. That's correct.

Q. You are Vyera's senior vice-president and head of research and development?

A. That's correct.

Q. As senior vice-president you're a member of Vyera's senior

leadership team?

A. Yes, I am.

Q. You report to Averill Powers?

A. Correct.

Q. Mr. Powers is the chief executive officer of Phoenixus?

A. Yes.

Q. He's also Vyera's general counsel and chief strategy officer?

A. That's correct.

MR. MEIER: Just for the record, Phoenixus is spelled P-h-o-e-n-i-x-u-s.

A. Yes.

Q. Your role at Vyera involves regulatory affairs and quality assurance?

A. Among other things, yes.

Q. You have worked at Vyera since January 2015?

A. Yes.

Q. So you were working at Vyera when Vyera acquired the rights to Daraprim in August 2015?

A. Yes, I was.

Q. As best I can tell, are you one of the few Vyera employees who was at the company when it first acquired Daraprim is still at Vyera today?

A. I'm the only one.

Q. Great. That's what I thought.

Dr. Pelliccione, you have a Ph.D. in biochemistry from the Mt. Sinai School of Medicine?

A. Yes.

Q. You have, as Mr. Casey said, over 35 years of experience in the pharmaceutical industry?

A. Yes.

Q. And you've devoted much of your career to assisting life science companies navigating regulatory challenges?

A. Yes, that's correct.

Q. When we say regulatory challenges, you're talking about meeting Food and Drug Administration rules and regulations?

A. Primarily, yes.

Q. And the Food and Drug Administration is often abbreviated as capital FDA?

A. Yes.

Q. When you first started working at Vyera, you reported to Dr. Eliseo Salinas?

A. Actually, when I first started working, I reported to Martin Shkreli.

Q. But when Dr. Salinas was hired, you began to report to Dr. Salinas?

A. That is correct.

Q. Speaking of Mr. Shkreli, when you first started working at Vyera, Martin Shkreli was Vyera's CEO?

A. I believe that's correct, yes.

Q. Did you meet Mr. Shkreli as part of the interview process when you were considering taking the job with Vyera?
A. Yes, I did.
Q. Did Mr. Shkreli interview you?
A. Yes, he did.
Q. While working at Vyera, you would meet with Martin Shkreli, is that correct?
A. On occasion, yes.
Q. About how many times do you estimate that you have met about Martin Shkreli while working at Vyera?
A. I don't know that I could hazard to guess. There were some regular meetings and then there were chance meetings.
Q. Are we talking about more than a hundred times?
A. I really couldn't answer that.
Q. While working at Vyera, you spoke with Mr. Shkreli many times?
A. I spoke with Mr. Shkreli on a number of occasions. I don't know how you would define many.
Q. Again, more than a hundred times?
A. Maybe not.
Q. While working at Vyera, you sent and received e-mails from Mr. Shkreli?
A. More than likely.
Q. Let's move away from talking about your professional background and talk briefly about a drug product called

Daraprim.

During your time at Vyera, you've had numerous responsibilities related to Daraprim, correct?

A. Well, anything related on a regulatory quality and R&D perspective, so, yes.

Q. Those types of responsibilities with respect to Daraprim came up on a number of different occasions during the time you have worked at Vyera?

A. Yes.

Q. Daraprim was first approved by the FDA in 1953?

A. That was the initial approval, yes.

Q. Daraprim is used today to treat toxoplasmosis?

A. That's correct.

Q. And the FDA approved Daraprim to treat toxoplasmosis in 1958?

A. That is correct.

Q. Toxoplasmosis is a potentially serious parasitic infection?

A. It's potentially serious. Potentially life threatening.

Q. Daraprim's active pharmaceutical ingredient is a chemical called pyrimethamine?

A. That's correct.

Q. The term active pharmaceutical ingredient is often abbreviated with capital API, is that correct?

A. Yes, that's correct.

Q. We are probably going to say that acronym a lot today,

right?
A. Yes.
Q. Daraprim is the gold standard treatment for toxoplasmosis, correct?
A. Daraprim is the only FDA-approved treatment for toxoplasmosis.
Q. Did you ever hear Mr. Shkreli say that Daraprim is the "gold standard" treatment for toxoplasmosis?
A. I can't say that I specifically heard Mr. Shkreli say that.
Q. Have you ever heard anyone at Vyera say that Daraprim is the gold standard treatment for toxoplasmosis?
A. I don't know that I could specifically state that I have heard anyone say that at Vyera.
Q. Have you ever said that?
A. I may have. I don't know. It's the only treatment.
Q. Fair to say that Vyera's revenues have principally been derived from the sales of Daraprim?
A. That's my understanding.
Q. Vyera only sells two products commercially, correct?
A. That is correct.
Q. One is Daraprim and the other is a product called Vecamyl?
A. Yes.
Q. Just to be sure, Vecamyl V-e-c-a-m-y-l?
A. That's correct.
Q. And Daraprim is a much larger product for Vyera than

Vecamyl, correct?

A. I believe from a revenue perspective, yes.

Q. You've been working at Vyera for almost seven years?

A. Yes.

Q. So during your time you've been working at Vyera, most of the company's profits have come from the sales of Daraprim?

A. I assume so. I'm not part of the finance area.

THE COURT: Doctor, let's be frank here. Do you have any reason to believe it's not principally from Daraprim?

THE WITNESS: No. I don't have any reason not to believe that.

MR. MEIER: Thank you, your Honor.

Q. Would it be fair to say that your salary at Vyera has mostly come from the sales of Daraprim?

A. I assume so.

Q. What is your current salary at Vyera?

A. $360,000.

Q. You've typically received an annual bonus while working at Vyera?

MR. CASEY: Your Honor, I am not sure what the relevance is to these questions.

THE COURT: Overruled.

Q. Let me ask that again. You've typically received an annual bonus while working at Vyera?

A. We did not always receive annual bonuses, but, yes, I have

received annual bonuses.

Q. What's the largest annual bonus you ever got at Vyera?

A. Probably this past year. I believe it was 25 percent of my salary.

Q. So 25 percent of your salary is about $90,000?

A. I believe that's correct.

Q. So your bonus at Vyera, that's mostly come from the sales of Daraprim, correct?

A. I assume so.

Q. You worked at Vyera when Mr. Shkreli raised the price of Daraprim by 4,000 percent?

A. Yes.

Q. Did you ever hear Mr. Shkreli say words to the effect that he should have raised the price of Daraprim even higher?

A. I did not hear him say that, but I have read that.

Q. Did you ever hear Mr. Shkreli say words to the effect that I could have raised the price of Daraprim even higher and made more profits for our shareholders?

A. Again, I don't recall that I heard him say that, but I have read that.

Q. And you are a shareholder of Vyera's parent company, Phoenixus, correct?

A. Yes, I am.

Q. As part of your compensation for working at Vyera, you've been given shares in Phoenixus?

A. Yes, I have.
Q. As of December 2020, you own more than 17,000 shares of Phoenixus, correct?
A. I think honestly -- I don't remember how many shares.
Q. But you do hold shares?
A. I do.
Q. And you hold the voting rights for some of those shares, correct?
A. Correct.
Q. And Mr. Shkreli holds the voting rights to some of your shares in Phoenixus, correct?
A. I believe that's correct.
Q. Let's talk about your role in Vyera's efforts to enter into an exclusive supply contract with a Japanese API supplier called Fukuzyu. Are you with me?
A. Yes.
MR. MEIER: For the record Fukuzyu --
THE COURT: I think it's on the glossary.
MR. MEIER: Your Honor, would it be better if I stopped spelling things?
THE COURT: I think I have gotten counsel into the good/bad habit of spelling for the court reporters. I think it's whenever I think that it might not be on the glossary.
MR. MEIER: Thank you, your Honor.
Q. You're familiar with a Japanese company called Fukuzyu?

A. Yes, I am.

Q. And Fukuzyu is at times abbreviated in documents as capital FKZ?

A. Correct.

Q. As part of the process of working with the FDA when you were transitioning the Daraprim new drug application from impacts to Vyera, you learned that Impax had been obtaining its pyrimethamine API from Fukuzyu, correct?

A. Yes, it's part of the NDA.

Q. And it is you that had noticed that in the NDA?

A. That is correct.

Q. NDA is an abbreviation for new drug application?

A. Yes.

Q. A new drug application that's used to describe the collection of regulatory filings that a pharmaceutical company has to make to get FDA approval to market a new drug?

A. Pretty much, yes.

Q. And you were actually the first person from Vyera who contacted Fukuzyu, correct?

A. That is correct.

Q. And you contacted Fukuzyu because Vyera needed to establish contact with them as the listed API supplier in the NDA?

A. Yes, that's correct.

Q. And you personally initially reached out to Fukuzyu in April of 2016?

A. I believe that's correct.
Q. And Fukuzyu is Vyera's supplier of pyrimethamine API today?
A. Yes, it is.
Q. And Fukuzyu is an important partner for Vyera?
A. Yes.
Q. Is it correct that no one from Vyera's business development team was involved in reaching out to Fukuzyu in April 2016?
A. As far as I know, yes.
Q. Now, in October of 2016, you personally visited Fukuzyu's facility in Japan, correct?
A. With two of my colleagues, yes.
Q. You were joined on the trip to Japan by your boss at the time, Dr. Salinas, and by a person named Gopal Krishna?
A. Yes, that's correct.
Q. That one I am not sure if you have the spelling. G-o-p-a-l K-r-i-s-h-n-a.

Dr. Salinas was Vyera's president and head of research and development at the time?
A. Yes.
Q. You now have his job?
A. I don't have the president job.
Q. Thank you.

In effect, Dr. Salinas was Vyera's senior most scientist at the time, correct?
A. Yes, that's correct.

Q. Mr. Krishna was Vyera's vice-president of chemistry, manufacturing, and control?
A. Yes, that's correct.
Q. And the term chemistry, manufacturing, and control is often abbreviated as capital CMC, correct?
A. Yes.
Q. And you were Vyera's senior vice-president for regulatory affairs at the time of the visit to Japan?
A. That's correct.
Q. So the three people Vyera sent to meet with Fukuzyu were the company's most senior people responsible for science, manufacturing, and regulatory affairs?
A. Yes.
Q. And no one from Vyera's business development team visited Fukuzyu in Japan with you in 2016, correct?
A. That is correct.
Q. As part of your visit to Japan you toured the plant where Fukuzyu makes pyrimethamine API?
A. Yes, we did.
Q. You took the plant tour because it's important for a manufacturer who is having a product manufactured by someone else to assure themselves that it is being made in a so-called GMP facility and under good conditions?
A. Well, I'd like to.
THE COURT: Is that a yes or a no? If you can answer

yes or no, you should do so. If you need to explain your answer, you'll have an opportunity to do so on cross-examination. If you can't answer it yes or no, of course, you may give a brief instruction or explanation.

A. Can I hear the question again, please?

Q. Yes. You took the plant tour because it's important for any manufacturer who is having a product manufactured by someone else to assure themselves that it is being made in a so-called GMP facility and under good conditions?

A. Technically, yes.

Q. Thank you.

You actually said that in your investigational hearing. Do you remember that?

A. No.

THE COURT: I don't think we have an answer to that for the record.

THE WITNESS: Off the top of my head, I don't remember.

Q. GMP stands for good manufacturing practices, correct?

A. Yes, it does.

Q. And the term good manufacturing practices is often abbreviated as capital G, M, and P?

A. Yes.

Q. And good manufacturing practices are regulations enforced by the FDA to assure the proper design monitoring and control

of pharmaceutical manufacturing processes and facilities?

A. That is correct.

Q. Sometimes the acronym GMP is preceded by the letter C, correct?

A. Yes.

Q. And the C stands for current, correct?

A. That is correct.

Q. So when you see CGMP, it means the most current good manufacturing practices that the FDA requires?

A. That's correct.

(Continued on next page)

BY MR. MEIER:

Q. You thought it was important that the specific team of people from Vyera who attended the meetings with Fukuzyu go on the plant tour?

A. Yes.

Q. And you wanted to be there specifically because you were responsible for regulatory affairs and quality assurance?

A. Yes.

Q. And Gopal Krishna wanted to be there because he was the head of CMC and you were touring a manufacturing plant?

A. Yes.

Q. And Dr. Salinas wanted to be there because he was the head of R&D and he actually oversees the whole operations for Vyera?

MR. CASEY: Your Honor, I object to the question. He's asking about what Mr. Salinas wanted to do. It's not within the knowledge of the witness.

THE COURT: Overruled.

THE WITNESS: Yes.

BY MR. MEIER:

Q. Thank you.

And no one from Vyera's business development team took the Fukuzyu plant tour with you?

A. That's correct.

Q. As part of your visit to Japan, you also met with Fukuzyu's technical personnel responsible for making pyrimethamine API?

A. I believe we did some of them anyway.
Q. And, again, no one from Vyera's business development team met with Fukuzyu's technical personnel responsible for making API?
A. That's correct.
Q. Let's now talk about the master services agreement between Vyera and Fukuzyu.
You were part of Vyera's team responsible for getting the agreement with Fukuzyu to supply Vyera with pyrimethamine API, correct?
A. Yes.
Q. And this role included reading the documents related to the master services agreement?
A. Yes.
Q. And your role included making sure that the agreement made sense?
A. Part of it, yes.
Q. And your role included making sure that certain things were included in the agreement, like the quality agreement?
A. The quality agreement is referred to in the service agreement, yes.
Q. So your role included making sure that certain things were included in the agreement, like the quality agreement?
A. Yes.
Q. And Vyera entered into the master services agreement with

Fukuzyu in January of 2017?
A. That's correct.
Q. And Vyera's agreement with Fukuzyu includes an exclusivity provision?
A. Yes.
Q. And Vyera didn't coerce Fukuzyu to include the exclusivity provision in the master services agreement, correct?
A. That's correct.
Q. Instead, Vyera made it financially attractive for Fukuzyu to enter the exclusivity agreement, correct?
A. I can't answer that.
Q. Well, let me ask you this: As part of the agreement, did Vyera offer Fukuzyu the prospect of supplying Vyera with additional pyrimethamine API -- I'm sorry, let me start that over.

As part of the agreement, Vyera offered Fukuzyu the prospect of supplying additional pyrimethamine API for future drug products Vyera was hoping to develop?
A. I don't believe that's part of the actual agreement.
Q. But that was part of the discussions with Fukuzyu, wasn't it?
A. That was part of -- we discussed the potential that Fukuzyu could do API development for us.
Q. In fact, that was discussed by you and Dr. Salinas with the people at Fukuzyu, correct?

A. Yes.
Q. And Fukuzyu had an understanding that there may have been future developed products that would require pyrimethamine and that Vyera would buy that pyrimethamine from Fukuzyu?
MR. CASEY: Objection, your Honor. I don't know that the witness can testify to Fukuzyu's understanding. A proper foundation hasn't been laid.
THE COURT: Sustained.
BY MR. MEIER:
Q. As part of the agreement, Vyera offered Fukuzyu a better price for pyrimethamine API than potential generic Daraprim manufacturers would, correct?
A. I don't know that.
Q. Okay.
MR. MEIER: Ms. Guy, would you please put Government Exhibit 1020 on the screen. Hopefully, the technology is working.
Q. If you could take a moment to just look at that first page?
THE COURT: So do you have the ability to enlarge the text?
Thank you.
MS. GUY: You're welcome.
BY MR. MEIER:
Q. Let me ask you this first Dr. Pelliccione.
A. Excuse me. Is it up? Because there's no -- it flashes up,

and then it goes away.

Q. Okay.

MR. MEIER: I don't know about courtroom technology. Do we need to bring somebody in to help with that, your Honor?

THE COURT: So I ask counsel to test the equipment in advance of each day's session. We'll ask my deputy to come and try to assist and, if necessary, courtroom support. So why don't you continue, counsel.

BY MR. MEIER:

Q. Do you see it up there now?

A. No.

MR. MEIER: Unfortunately, your Honor, when we got ready for this trial, the rule was we had to put everything up, so I didn't have time to put together binders, and I do not have a backup other my own personal copy that's been highlighted. I'm happy to give the witness my personal highlighted copy.

THE COURT: I don't think that's necessary for this document. I think you can go ahead.

MR. MEIER: Okay.

BY MR. MEIER:

Q. Well, Dr. Pelliccione, do you know whether you have seen the document marked as Government Exhibit 1020 before?

A. I do not know.

MR. MEIER: Okay. I'm not sure if I can continue with

this, then. We'll have to put that one aside, and I will come back to that. Apologies, your Honor. We'll do better tomorrow, I hope.

BY MR. MEIER:

Q. As part of your role at Vyera, you were responsible for helping make sure that Fukuzyu was compliant with the master services agreement, correct?

THE COURT: Put the document back up again, please.

MS. GUY: Yes. I was just seeing if it would --

(Pause)

THE COURT: Okay, counsel, why don't you continue. We're going to be assisted in a moment with technical -- oh, maybe they're here.

So we're having trouble -- counsel is having trouble displaying the image on the witness' screen. It's on my scene, and it's on counsel's screens.

MR. MEIER: It appears to be working everywhere except for the witness, your Honor.

(Pause)

THE COURT: So, Mr. Whertvine, if you would watch what technical changes are being done, that would be of assistance.

You'll be happy to know this isn't coming off your time.

MR. MEIER: Okay. Thank you, your Honor. It's a huge relief. I was about to ask Mr. Albert to rearrange our

schedules.

(Pause)

THE COURT: We're going to take a midmorning recess. A cable needs to be replaced. Let's make it ten minutes, I think.

Okay, good. Have a nice break.

(Recess)

MR. MEIER: Thank you, your Honor. Again, Markus Meier, for the Federal Trade Commission.

We have put up on the screen Government's Exhibit 1020.

BY MR. MEIER:

Q. Do you see that now, Mr. Pelliccione -- Dr. Pelliccione?

A. Yes, I do.

MR. MEIER: If we could briefly put the cover email up.

MS. GUY: Working on it.

Now, the technical difficulties have --

(Pause)

MR. MEIER: Again, your Honor, I appreciate the Court's indulgence, and, hopefully, we'll work through these kinks and not have this happen a whole lot more.

BY MR. MEIER:

Q. Dr. Pelliccione, do you see the cover email here?

A. Yes, I do.

Q. And the emails from Gopal Krishna, correct?
A. Yes.
Q. And it's to you and Adam Bloom, correct?
A. Yes.
Q. And the subject is master services agreement?
A. Correct.
Q. And it attaches the Fukuzyu-Turing master services agreement executed. Do you see that?
A. Yes.
Q. Have you seen Government Exhibit 1020 before?
A. That's the MSA?
Q. Yes. And this email.
A. I've probably seen the email, but, yes, I've seen the MSA.
Q. So what is Government Exhibit 1020?
THE COURT: Is that the email or the MSA?
MR. MEIER: Well, the email -- the MSA is attached to the email, your Honor.
THE COURT: Okay. But on the screen, I don't think you see an exhibit number. So the witness may not know what you're referring to when you use the exhibit number.
BY MR. MEIER:
Q. So the exhibit --
A. I see it.
Q. -- Dr. Pelliccione, is both the email with the MSA attached.

A. You're asking have I seen this?
Q. Yes, I've asked you have you seen it, and then I'm asking you what it is.
A. Okay. So, yes, I've seen it, and it is the service agreement between Turing and Fukuzyu for pyrimethamine API.
Q. Thank you.
MR. MEIER: Your Honor, I move to admit Government Exhibit 1020 in evidence.
THE COURT: Received.
(Government's Exhibit 1020 received in evidence)
BY MR. MEIER:
Q. Let's -- now, hopefully, this will work. Let's look at the first page of Government Exhibit 1020, the actual agreement now.
Do you see that?
A. Yes. It's a little blurry and small.
Q. Okay. We'll work on that.
MR. MEIER: Now I'd like to move to the upper half of the second page, if that can work.
I missed my own cue. Let's, actually, look at the upper half of page 14. Sorry.
I'm sorry, page 14 of the master services agreement, which is page 15 of the exhibit.
Again, apologies as we work through this.
Q. Do you see that page?

A. Yes, I do.
Q. So this is the executed version of the master services agreement?
A. Yes, it is.
Q. And Mr. Tilles was the chief executive officer of Turing at the time?
A. Yes.
Q. And Mr. Kosugi was the president of Fukuzyu at the time?
A. Yes.
Q. Is it correct that Mr. Tilles actually went to Japan to sign the master services agreement with Mr. Kosugi on January 25, 2017?
A. I'm not sure about that.
Q. Okay, all right.

MR. MEIER: You can take that down, Ms. Guy.

Your Honor, I apologize. I asked to have this admitted. I don't remember if I got a ruling on that.

THE COURT: Yes, it was received.

MR. MEIER: Thank you, your Honor.

BY MR. MEIER:
Q. As part of your role at Vyera, you were responsible for helping Fukuzyu make sure that it remained compliant with the agreement, correct?
A. I'm not entirely sure what you mean.
Q. Well, from time to time, Fukuzyu would check with you to

make sure that it was still abiding by certain terms in the master services agreement, correct?

A. Yes.

MR. MEIER: So, actually, I'd like to pull it up again and look at the very top of page 4 of the master services agreement. If we could blow up paragraph (b) there.

BY MR. MEIER:

Q. Do you recognize what paragraph (b) is on page 4 of Government Exhibit 1020?

A. Yes.

Q. What is it?

A. It's the provision for exclusivity for Fukuzyu to provide the pyrimethamine to Turing.

Q. And you understood the term "territory" to mean United States?

A. Yes.

Q. And you understood that the exclusivity only applied to the use of pyrimethamine API for humans only?

A. Yes.

Q. So Fukuzyu could still sell API in the United States for animal use?

A. If they chose to, yes.

Q. And one of your roles at Vyera was to make sure Fukuzyu remained compliant with this exclusivity provision, correct?

A. It wasn't really my role.

Q. But Fukuzyu would check with you through a person named Mr. Arisawa, correct?

A. Mr. Arisawa would basically send everything through me.

Q. Right.

A. He was the liaison with us.

Q. So Mr. Arisawa was Vyera's representative in Japan, correct?

A. Yes, that's correct.

Q. And Mr. Arisawa would assist Vyera in its negotiations and relations with Fukuzyu?

A. In the sense that we would provide him with information to bring back to Fukuzyu.

Q. Right.

And Mr. Arisawa speaks Japanese?

A. Yes.

Q. And he's somebody you knew from a position you had before you came to Vyera?

A. That is correct.

Q. And it was you who had reached out to Mr. Arisawa to develop a relationship for him to act as Vyera's representative in Japan, correct?

A. That's correct.

Q. And, from time to time, Mr. Arisawa would send you questions from Fukuzyu about the interpretation of this exclusivity provision, correct?

A. That was done, yes.
Q. And one of the outcomes of this exclusivity provision was to prevent generic manufacturers in the United States from acquiring pyrimethamine API from Fukuzyu for human use, correct?
A. That would have been an outcome, it would have prevented any manufacturer that wanted the API.
Q. To use the API for human use in the United States?
A. In the United States.
Q. This outcome was beneficial for Vyera in the sense that Vyera would have less competition?
A. In essence, I guess, yes.
Q. I don't want you to guess. Could you just say whether that's correct or not?
A. That would be correct.
Q. Thank you.
MR. MEIER: We can take that exhibit down, and I would ask Ms. Guy to pull up Government Exhibit 1019.
Actually, I'm going to --
BY MR. MEIER:
Q. Can you see this, Dr. Pelliccione --
A. Yes.
Q. -- or do we need to blow it up?
If you could take just a quick moment and familiarize yourself with it before I ask a couple of questions.

Again, I'm not asking you about -- I'll ask you about some specific sentences, but I just want you to get a sense of what this actually is.

Here's my question, Dr. Pelliccione --

A. Yes.

Q. -- have you seen the email chain that's marked as Government Exhibit 1019 before?

A. Yes.

Q. And what is Government Exhibit 1019?

A. It's a series of emails covering a couple of different things related to Daraprim.

Q. I don't know how to pronounce the name. It says it's from -- what's the name of the person?

A. Senajda.

Q. Senajda?

A. Celaj.

Q. That's spelled S-e-n-a-j-d-a and the last name -- Celaj, you said?

A. Yes.

Q. -- is C-e-l-a-j.

Is Senajda Celaj a man or a woman?

A. A woman.

Q. Did Ms. Celaj send an email to you, Dr. Pelliccione?

A. Yes, she did.

MR. MEIER: Your Honor, I would move to admit

Government Exhibit 1019 in evidence.

THE COURT: Received.

(Government's Exhibit 1019 received in evidence)

MR. MEIER: Let's turn to page 2 of Government Exhibit 1019.

BY MR. MEIER:

Q. I'm going to ask you about the fifth line down, where it says, "On November 22, 2016, at 7:31 a.m."

Do you see that?

A. Yes, I do.

Q. Let me read the entire line there. "On November 22, 2016, at 7:31 a.m., Nick Pelliccione," and it has your email address, "wrote the following." After the greeting, where it says, "Morning Senajda," you write, "We got good news from Mikio in Japan overnight — Fukuzyu has accepted our agreement to provide pyrimethamine exclusively for us for human drugs and will not sell to generic manufacturers. That is a big sigh of relief for us!"

Do you see that?

A. Yes.

Q. And you wrote that email, correct?

A. Yes.

Q. When it says Mikio, M-i-k-i-o, that's Mikio Arisawa?

A. Correct.

Q. Again, Mr. Arisawa was your representative in Japan?

A. Yes.
Q. And Mr. Arisawa helped you negotiate the exclusivity agreement with Fukuzyu?
A. Yes. He served as our liaison.
Q. Still looking at Government Exhibit 1019, "Our agreement" in that sentence refers to the master services agreement?
A. Yes.
Q. And that's the agreement for Fukuzyu to supply pyrimethamine API to Vyera for use in making Daraprim?
A. Yes. Vyera in the sense that at the time, it was Turing, but, yes.
Q. When it says "will not sell to generic," when you wrote that, that means that under the agreement between Fukuzyu and Vyera, Vyera -- I'm sorry, let me start that over.

Where it says "will not sell to generics," that means that under the agreement between Fukuzyu and Vyera, Fukuzyu agreed not to sell pyrimethamine API to any generic companies in the United States that might compete with Vyera, correct?
A. It's correct in that generic manufacturers are among pharmaceutical manufacturers in the United States, but it would have excluded any pharmaceutical manufacturer in the United States.
Q. I appreciate that.

So not just the generic manufacturers were excluded, but anybody who might want to make pyrimethamine in competition

with Vyera?

A. Only to use Fukuzyu's pyrimethamine.

Q. Right. Got it. Thank you.

And then you say, "That is a big sigh of relief for us!"

And by that, you were relieved that Fukuzyu had agreed not to sell pyrimethamine to any of Vyera's competitors in the United States, correct?

A. I don't know that that's specifically what I meant. We were very relieved that we had finally gotten to an agreement that was going to be signed.

Q. All right.

MR. MEIER: Let's turn to page 1 of Government Exhibit 1019 and the middle of the page, and let's see if Ms. Guy can call that up.

BY MR. MEIER:

Q. Do you see that on your screen?

A. Yes.

Q. This is later in the day, around 8:18 a.m., still on November the 22nd, correct?

A. Yes.

Q. Do you see where you wrote, "The Fukuzyu thing is great for us!" It's actually the third paragraph down.

A. Yes.

Q. You write, "The Fukuzyu thing is great for us!"

"The Fukuzyu thing" means the exclusive API agreement between Vyera and Fukuzyu, correct?

A. It means the supply agreement.

Q. Right.

With the exclusivity provision?

A. That's part of it, yes.

Q. Thank you.

MR. MEIER: Ms. Guy, you can take Government Exhibit 1019 down. Thank you.

Q. As Part of the contract, or the agreement, with Fukuzyu, Vyera didn't make any investment in developing Fukuzyu's manufacturing process for API, did it?

A. No.

Q. And Vyera didn't discover Daraprim?

A. No.

Q. And Vyera doesn't actually make or manufacture Daraprim, correct?

A. You mean as an actual manufacturer?

Q. That's right.

A. No, we don't manufacture anything.

Q. Vyera uses a third-party contracted manufacturing organization to make Daraprim, correct?

A. Correct.

Q. Vyera doesn't actually manufacture the active pharmaceutical ingredient in Daraprim, correct?

A. That's correct.
Q. Fukuzyu does?
A. Yes.
Q. And Vyera doesn't distribute pyrimethamine API in the United States or anywhere else in the world, does it?
A. No.
Q. Vyera uses a third party to distribute Daraprim for it?
A. Daraprim, the product?
Q. The product.
A. Yes.
Q. The pill, Daraprim, is distributed for Vyera by another company?
A. Correct.
Q. But Vyera does set the price of Daraprim, correct?
A. Apparently, yes.
Q. I'm sorry, what?
A. Apparently, yes.
Q. Okay. Thank you.

Your responsibilities for working with Fukuzyu didn't end after the two companies signed the exclusive agreement, correct?
A. That's correct.
Q. You continued to be involved primarily for issues of regulatory and quality issues?
A. That's correct.

Q. And, again, you would work sometimes with your representative in Japan, Mr. Arisawa, correct?
A. Correct.
Q. He continued to assist you with those types of issues as a go-between from Vyera to Fukuzyu?
A. Yes.
Q. So, under the exclusivity provision of the contract, Vyera gets to decide which, if any, companies in the United States may buy pyrimethamine API from Fukuzyu?
A. If Vyera were going to agree to have another company purchase the API, that would be correct.
Q. Right.

MR. MEIER: Ms. Guy, would you please put Government Exhibit 1003 on the screen. Thank you.

Q. Would you take a moment to just get a general sense of it. I'm going to ask you some specific questions, but the first thing I'm going to ask you, as I always will, is: Have you seen this before and what is it?
A. Well, yes, I have seen it before. It's a fairly old email.

Could you make it a little bigger or darker.

MR. MEIER: Let's just make the top part a little bigger.

THE WITNESS: Thank you.

It's regarding supplying pyrimethamine to another company.

BY MR. MEIER:

Q. And it's an email chain between you and your representative in Japan, Mr. Arisawa, correct?

A. That's correct.

MR. MEIER: Your Honor, I move to admit Government Exhibit 1003 in evidence.

THE COURT: Received.

MR. CASEY: Your Honor, on that point, if I may, the emails that are coming from Mr. Arisawa, we would submit, are hearsay. We object to the admission on that basis.

MR. MEIER: Your Honor, I think it's been well established that Mr. Arisawa was an agent for Vyera in Japan and continued to work with Vyera as Vyera's agent in negotiations and then in the further efforts to make sure that Fukuzyu complied with the agreements.

THE COURT: Overruled.

MR. MEIER: Thank you, your Honor.

THE COURT: Received.

(Government's Exhibit 1003 received in evidence)

MR. MEIER: Thank you, your Honor.

BY MR. MEIER:

Q. I'm going to start with the earliest email, which actually is the one at the back, because as often is the case, you go in sort of reverse chronological order, and I want to do it in chronological order. So we're going to start with the earliest

one in the chain, the one at the bottom of page 1, which is from Mr. Arisawa to you. And I see Ms. Guy has pulled that up.

Do you see where it says, "Hi Nick"?

A. Yes.

Q. And, again, "FKZ" is Fukuzyu?

A. Yes.

Q. So Mr. Arisawa writes, "Hi Nick. Fukuzyu was approached by an American pharmaceutical company called APTRICA for the supply of pyrimethamine API for generic use."

Do you see that?

A. Yes, I do.

Q. "For generic use" meant that APTRICA wanted to buy pyrimethamine API from Fukuzyu to make a generic Daraprim in competition with Vyera, correct?

A. Apparently, yes.

Q. And moving up to page 1 of Government Exhibit 1003, do you see your email in response? And Ms. Guy is going to blow that up for you?

A. Yes.

MR. MEIER: Let's get that centered. There we go.

Q. Do you see that?

A. Yes, I do.

Q. And you wrote, "Dear Mikio, I can confirm that the company you mention below, APTRICA, is not affiliated with Vyera in any way."

Do you see that?

A. Yes.

Q. You didn't want a generic competitor to get access to pyrimethamine API, correct?

A. That was not the question I was asked. It was whether or not APTRICA was affiliated with Vyera, and they were not.

THE COURT: So can you answer the question that was asked by counsel?

THE WITNESS: Can you repeat the question?

BY MR. MEIER:

Q. My question was: You didn't want a generic competitor to get access to the API to make Daraprim, correct?

A. We didn't want another American pharmaceutical company as part of the exclusivity agreement. That was basically the fact.

Q. Right.

So, actually, we'll take a look at the top of page 1 of Government Exhibit 1003.

Mr. Arisawa writes back to you, "I passed your message to Fukuzyu and asked not to supply pyrimethamine to APTRICA."

Do you see that?

A. Yes.

Q. So Mr. Arisawa understood that you didn't want Fukuzyu to sell pyrimethamine API to a generic competitor in the United States, correct?

MR. CASEY: Objection. Your Honor --

THE COURT: Overruled.

THE WITNESS: Yes, that's correct.

BY MR. MEIER:

Q. Okay.

MR. MEIER: Ms. Guy, you can take Government Exhibit 1003 down. Thank you.

Ms. Guy, would you please put Government Exhibit 1005 on the screen. Thank you.

Q. Again, just take a moment, to the extent you can read this, to just get familiar with it, and I'm going to start by asking you: Have you seen it before? And what is it?

A. Yes, I've seen it before.

And it is a series of emails between Dr. Arisawa and myself regarding pyrimethamine sale -- pyrimethamine API sale to a company called Sanyo.

MR. MEIER: Okay. Your Honor, I move to admit Government Exhibit 1005 in evidence.

THE COURT: Received.

(Government's Exhibit 1005 received in evidence)

BY MR. MEIER:

Q. Again, let's start with the earliest email in the chain, which is the bottom of page 2, and it appears to be from Mr. Arisawa to you.

Do you see that, Dr. Pelliccione?

A. Yes, I do.
Q. I'm sorry. A moment ago, I think I heard you say Dr. Arisawa?
A. Yes.
Q. Is that actually his correct title?
A. That is correct.
Q. Okay. I'll try to remember that.
Do you see where it says, "Hi Nick"?
A. Yes.
Q. Then it says, "Fukuzyu informed me that they are selling PYR to a Japanese trading company called Sanyo."
Do you see that?
A. Yes.
Q. And PYR would be pyrimethamine?
A. Yes.
Q. Reading the rest of it, "which, in turn, planned to sell it to an American pharma that intends to develop it for South America."
Do you see that?
A. I do.
Q. And it says, "Fukuzyu judged that this contract would not interfere with the exclusivity term in the SA with you because the exclusivity is confined to the U.S. market."
Do you see that?
A. I do.

Q. And "SA," that's an abbreviation for the master services agreement?

A. Yes.

Q. Then it says, "Fukuzyu does not know where the American company plans to conduct clinical trials for development. In other words, it might conduct clinical trials in the U.S. No information," correct?

A. That's correct.

Q. So what I'd like to do is continue to look at this Government Exhibit 1005, but I'd like to move to the middle of the page of page 1, where you write back.

Do you see that blown up?

A. Yep.

Q. And you're following up on that email from Mr. Arisawa that informs you that a Japanese trading company called Sanyo wants to acquire pyrimethamine for a company in the United States, correct?

A. That's correct.

Q. So you write back -- do you see where it says, "in order for us"?

A. Yes.

Q. Okay. Sorry, but this is going to be a little bit long, but it says, "In order for us to be sure there is no breach of contract here, we would need assurances in the form of representations and warrants in their contract with Sanyo that

the API sold to the U.S. company will not be used to make pyrimethamine drug product for human use that will find its way back to the U.S. for commercial purposes, either via normal prescription drug distribution or via 'compounded drug products' or 'compounding pharmacies.'"

Do you see that?

A. Yes, I do.

Q. Do you recall how Mr. Arisawa responded back to you on this?

A. I believe -- no, I don't recall exactly, no.

Q. All right. Then let's take a look at the top of Government Exhibit 1005, the third paragraph.

Mr. Arisawa writes, "She replied" -- I'm sorry, let me give you -- do you see where it says, "she replied"?

A. Yes.

Q. "She replied saying Fukuzyu understand to put such words in the contract," correct?

A. That's what it says, yes.

Q. So you were instructing Mr. Arisawa to instruct Fukuzyu that before it could sell API to a Japanese company called Sanyo, Vyera needed assurances that the API it was selling to Sanyo, that Sanyo was going to send to an American company, would not find its way back into the United States, correct?

A. That is correct, yes.

Q. You wanted to make sure that if Fukuzyu sells pyrimethamine

API to another American pharmaceutical company, that none of that ends up in the United States?

A. We wanted to make sure they were adhering to the exclusivity agreement, yes.

Q. And you wanted to make sure that none of the pyrimethamine ends up competing in some way with Vyera's Daraprim?

A. Ultimately, that would be the case.

MR. MEIER: We can take that down, please.

Q. Have you ever heard of a person named Akeel in a then?

A. Yes.

MR. MEIER: Akeel is spelled A-k-e-e-l.

Q. Who is Mr. Mithani?

A. Right now?

Q. Sure.

A. He is business development -- he is in the business development group — actually, the head of business development now — at Vyera.

Q. And Mr. Mithani is not a chemist, correct?

A. I do not believe he is, no.

Q. And as far as you know, Mr. Mithani doesn't have any background in pharmaceutical chemistry, manufacturing, or controls, correct?

A. As far as I know.

Q. And as far as you know, Mr. Mithani doesn't have any background in pharmaceutical regulatory affairs?

A. Correct.
Q. In fact, you don't know what Mr. Mithani's background is other than business development?
A. That's correct.
Q. And as you said, Mr. Mithani is part of Vyera's business development team, and today, is actually the head?
A. Correct.
Q. Do you know the circumstances of how Mr. Mithani was hired by Vyera?
A. No, I do not.
Q. Do you know whether it was Mr. Shkreli who had any role in getting Vyera to hire Mr. Mithani?
A. I don't know for sure, no.
Q. But you do know that Mr. Mithani eventually became one of the directors of the board of directors for Phoenixus?
A. Yes.
Q. Did you vote your shares in Phoenixus to put Mr. Mithani on the board?
A. I don't recall.
Q. Do you know whether Mr. Shkreli voted his shares in Phoenixus to put Mr. Mithani on the board?
A. I do not.
Q. Have you ever heard of a person named Kevin Mulleady?
A. Yes.
Q. Who is Kevin Mulleady?

A. I do not know what he does now, but back several years ago, he was an employee of Vyera.
Q. He was actually, at one point, Vyera's CEO?
A. Yes.
Q. And when Mr. Mulleady was Vyera's CEO, you reported to him?
A. Yes.
Q. And Mr. Mulleady is not a chemist, is he?
A. I don't believe he is, no.
Q. And Mr. Mulleady doesn't have any background in pharmaceutical chemistry, manufacturing, and controls?
A. I don't believe so.
Q. And Mr. Mulleady doesn't have any background in pharmaceutical regulatory affairs?
A. I don't believe so.
Q. In fact, you don't know what Mr. Mulleady's background is other than business development, do you?
A. I don't know that -- I don't know that Mr. Mulleady's background is business development. I do know he has a degree in aerospace engineering, but, other than that, I don't know what his actual role is.
Q. Do you know whether Mr. Mulleady was ever part of Vyera's business development team?
A. I don't recall that.
Q. Do you know the circumstances of how Mr. Mulleady was hired by Vyera?

A. No, I don't.
Q. Do you know whether Mr. Shkreli had any role in getting Vyera to hire Mr. Mulleady?
A. No, I do not.
Q. Do you know how Mr. Mulleady came to be your boss at Vyera?
A. He was made executive director of the company and then ultimately CEO, so, by default, I reported to him.
Q. When you say he was made executive director of the company, you mean he was put onto the board of directors?
A. No, no. He was -- both Kevin Mulleady and Akeel Mithani were brought in as executive directors, and they were actually running the company together while there was no official CEO, to the best of my recollection.
Q. I understand. Okay, thank you.

And Mr. Mulleady also eventually became a member of the Phoenixus board of directors, correct?
A. I actually don't know that.
Q. You don't know? Okay.

I'm going to shift topics now. Based on your more than 35 years of experience working in the pharmaceutical industry, would you agree that APIs take time to develop?
A. Yes.
Q. And based on your experience, it could take two-plus years to develop an API from scratch?
A. It depends on the API.

Q. Sure.

Well, what about Daraprim API, if you were developing it from scratch, do you have a sense of how long that would take?

A. You mean to be able to use it in a pharmaceutical product?

Q. Right.

From the time you start the project to the time you can put it into a pharmaceutical product, do you have any idea how long that might take?

A. I mean, my best estimation would be that it would take somewhere between 12 and 18 months, at the earliest -- at the low end, and possibly more.

Q. Okay.

A. It's hard to tell.

Q. Sure. Understood.

But if you can find somebody with a drug master file on file with the FDA, the process could go quicker, correct?

A. If you were to -- yes.

Q. Just so we're clear, a drug master file, that's a submission to the FDA used to provide detailed information about facilities, processes, and other articles used in the manufacturing of human drugs?

A. Yes.

Q. And the term "drug master file" is often abbreviated as capital DMF, correct?

A. That's correct.
Q. Now, there are a number of steps a company needs to take to develop an API, correct?
A. Yes.
Q. And you've had experience trying to do so, correct?
A. Well, I'm not a manufacturing chemist myself, but I've been involved in the development and the things that go into manufacturing an API, yes.
Q. Right.

I understand you're not a chemist; you're a regulatory affairs person?
A. At this point, yes.
Q. And you have been involved in that capacity in the development of an API, correct?
A. Correct.
Q. So the first step, you'd have to procure the raw materials that would be required for the synthetic or the chemical process, correct?
A. That would be among the first. First, you'd have to establish the -- you'd have to figure out how to make it, and that would tell you what your starting materials are.
Q. Okay.

And you have to establish the process and make sure you have the right equipment?
A. Correct.

Q. And you have to be able to do analytical work that's required to develop the specifications and test the product along the way?

A. Correct.

Q. Until you're able to develop the final product?

A. Yes.

Q. Are there any other sort of key steps in the process that I missed?

A. Those are the major categories.

Q. If you wanted to obtain pyrimethamine as an active pharmaceutical ingredient, if somebody wanted to, it would help to reach out to a company that already knows how to make it, correct?

A. Yes.

Q. And it would help to reach out to a company that has a U.S. DMF?

A. That would help, yes.

Q. And if you could reach out to a company that already had a U.S. DMF, that would shorten the process to getting approval to make a generic version, correct?

A. Yes.

Q. So would it be fair, to sort of summarize, that if you were looking for API, your preferences, in order, would be, number one, find an API supplier with a U.S. DMF for the drug product you want to make?

A. Yes.
Q. Number two would be to find an API supplier with a European DMF for the drug product you want to make?
A. I would not necessarily go look for a European DMF supplier.
Q. I understand.

I'm trying to -- I'm actually trying to get more sort of an hierarchy of if you were looking for an API supplier, and you couldn't find one with a U.S. DMF, would a European DMF be the next best substitute?
A. I don't know that that would be the case.
Q. Okay.

Well, what would be the next best? What would you do -- if you were looking for an API supplier and can't find anyone with a U.S. DMF, what would you do next to look for it?
A. I would go look at other API manufacturers and see if they can manufacture the API.
Q. Well, how would you do that?
A. You would send out proposals with information and ask them to reply whether or not they can do this, and then there's other steps after that.
Q. So you'd establish some kind of an RFP process?
A. More or less, yes.
Q. Request for proposal?
A. Correct.

Q. Have you ever heard of the Indian company called RL Fine?
A. I've heard of them.
Q. And RL Fine is a chemical manufacturer?
A. I believe that's correct, yes.
Q. And as far as you know, RL Fine makes APIs?
A. I believe they do.
Q. To the best of your knowledge, did RL Fine ever supply API to Vyera for Daraprim?
A. No.
Q. Were you involved in any negotiations with RL Fine about a pyrimethamine API agreement?
A. No.
Q. Is it correct that none of Vyera's senior-most people responsible for science, manufacturing, or regulatory affairs were involved in negotiations with RL Fine about a pyrimethamine API agreement?
A. I was not aware of any negotiations with RL Fine about an agreement for pyrimethamine API until, in preparing for this trial, it came up in discussions with my lawyers.
Q. Okay. Well, I'm not going to ask you about your discussions with lawyers.
A. Right.
Q. So it wasn't until preparing for this trial, that you have actually learned that Vyera has a contract with RL Fine or had a contract with RL Fine?

A. That's correct.
Q. All right. I'll move on.
Is it fair to say that it's standard procedure for Vyera that you typically have quality agreements with your API suppliers?
A. Yes.
Q. To the best of your knowledge, did Vyera ever have a quality agreement with RL Fine?
A. Not to my knowledge.
Q. And Vyera has a standard operating procedure which calls for the audit, roughly, every two to three years of your principal suppliers?
A. That's correct.
Q. Do you know whether Vyera ever conducted an audit of RL Fine?
A. I am not aware of that, no.
Q. Do you know whether Vyera's ever hired a third party to conduct a quality audit of RL Fine?
A. I am not aware of that, no.
Q. And you've never been involved in a quality audit of RL Fine, have you?
A. No.
Q. Shifting back to Fukuzyu:
Fukuzyu has been manufacturing API for Daraprim for a long time, correct?

A. I believe so.
Q. Do you have any idea of how long?
A. No.
Q. You don't recall that discussion coming up when you visited Japan?
A. It may have, but I don't recall.
Q. But it's correct, though, that Fukuzyu manufactures API not just for Vyera, but for many other companies around the world?
A. API in general or pyrimethamine?
Q. Pyrimethamine API. Sorry. Thank you.
A. I know they manufacture pyrimethamine API for other companies. I don't know how many.
Q. But you do know that they do that for companies all around the world, correct?
A. Yes.
Q. And Fukuzyu has consistently delivered quality API for Vyera?
A. Yes, they have.
Q. And you don't have any concerns about Fukuzyu's ability to comply with FDA regulations, do you?
A. At this point, no.
Q. And Fukuzyu has always provided sufficient pyrimethamine API to meet Vyera's needs?
A. Yes.
Q. And there's never been a time when Fukuzyu wasn't able to

provide Vyera with sufficient pyrimethamine, correct?
A. That's correct.
Q. In fact, Vyera hasn't had any issues with Fukuzyu in terms of supplying Vyera with all the Daraprim it needs, correct?
A. With all the API?
Q. I'm sorry, with all the Daraprim -- let me start that over.
Vyera hasn't had any issues with Fukuzyu in terms of supplying Vyera with all the Daraprim API it needs?
A. To this point, that's correct.
Q. You personally have never been involved in looking for a second supplier for pyrimethamine API, correct?
A. That's correct.
Q. And you haven't been involved in looking for a backup supplier for pyrimethamine API, correct?
A. That's correct.
Q. Why is that? Why haven't you ever been involved in looking for a backup supplier for pyrimethamine API?
A. It never crossed my thinking process that we would need a backup supplier for --
Q. You didn't think it was necessary?
A. -- pyrimethamine API.
It's just something that never was discussed, at least with me.
Q. Right.
So it never occurred to you that it might be necessary

to get a backup supplier for pyrimethamine API?

A. Right. I mean, typically, it's never really necessary to have a backup supplier.

Q. Okay. Let's talk a bit about some of your personal interactions with the FDA concerning Daraprim.

To the best of your knowledge, has there ever been a shortage of Daraprim in the United States?

A. To the best of my knowledge, no, there has not.

Well, you mean while with Vyera?

Q. Thank you for that clarification. Yes.

So let me ask it again, then.

To the best of your knowledge, there has never been a shortage of Daraprim in the United States during the time that Vyera has owned Daraprim; is that correct?

A. That's correct.

Q. Vyera was, however, contacted a couple of times by the FDA about a possible Daraprim shortage, correct?

A. That's correct.

(Continued on next page)

Q. When the FTC reached out to Vyera, they actually reached out to you?

A. Yes.

Q. Let me finish the question.

When the FDA reached out to Vyera about a possible shortage of Daraprim, they reached out to you because you were the senior regulatory person, correct?

A. If I may clarify, they reach out to me because I'm the official correspondent for the NDA.

Q. It happened on at least two separate occasions, correct?

A. I believe so, yes.

Q. One of them was early on after Vyera acquired the rights to Daraprim from Impax?

A. To the best of my recollection, yeah.

Q. Again, it might have happened a little more than a year or two ago?

A. I believe that's correct.

Q. I believe you were contacted by someone from the FDA drug shortages staff?

A. That's correct.

Q. And the FDA drug shortages staff, they monitor the nation's drug supply to prevent supply shortages or mediate in the event of a shortage, correct?

A. Yes.

MR. MEIER: Ms. Guy, would you please put up

Government Exhibit 1002 on the screen.

Q. Again, we will go through the same routine. If you could, to the best of your ability, take a look at that and figure out whether you have seen it before and what it is. Then I am going to ask you some specific questions.

A. Yes. I'm familiar with it. It's a series of e-mails between myself and Robert Kosko from the FDA about the Daraprim supply.

MR. MEIER: Your Honor, I move to admit Government Exhibit 1002 in evidence.

THE COURT: Received.

(Government Exhibit 1002 received in evidence)

Q. So this is several e-mails between you and Robert Kosko at FDA regarding a potential supply issue with Daraprim, correct?

A. Yes.

Q. And the FDA is asking you about a possible Daraprim shortage or supply issue because IQVIA data showed that the monthly supply for January to March of 2018 had decreased to single digits, correct?

A. That was his question, yeah.

Q. And IQVIA is spelled capital IQVIA, correct?

A. Yes.

Q. IQVIA is a data source often used by people in the pharmaceutical industry in the commercial and marketing areas, correct?

A. Primarily, yes.
Q. Did you ever learn why the IQVIA data underreported the sales data for Daraprim causing the FDA to reach out to you?
A. Not really.
MR. MEIER: Ms. Guy, you can take 1002 down and please put up 1013.
Q. Again, if you could take a moment to look at it.
A. OK.
Q. Does this refresh your recollection?
A. Yes.
Q. Before I ask you anything substantively about it, have you seen the document marked as Government Exhibit 1013 before?
A. Yes, I have.
Q. What is Government Exhibit 1013?
A. It's an e-mail exchange between me and Anne Kirby regarding, again, further information about the FDA's request about the supply.
MR. MEIER: Your Honor, I move to admit Government Exhibit 1013 in evidence.
THE COURT: Received.
(Government Exhibit 1013 received in evidence)
Q. Look at page 1 near the top, the sentencing start with: The inquiry is likely related. Do you see that?
A. Yes.
Q. This is an e-mail that Anne Kirby is sending to you,

correct?

A. Yes.

Q. Anne Kirby at the time, maybe even today, I am not sure, is the head of commercial operations for Vyera?

A. I believe that was the case.

Q. When we say commercial operations, what does commercial mean?

A. Sales.

Q. Sales. OK. Sales of the product.

So Ms. Kirby writes: The inquiry is likely related to the business decision we made to block dispense/sales data reported by our distribution partners, not an actual shortage in availability or distribution. Do you see that?

A. I do.

Q. Does that refresh your recollection as to what the reason was why the FDA was reaching out to you about a possible shortage?

A. It recollects, looking at the e-mail now, yes.

Q. What do you remember now?

A. Just that she told me this. I had really no part in that.

Q. I understand.

She is telling you that Vyera made a business decision to block Daraprim's sales data that was reported by its distribution partners to IQVIA, correct?

A. That is what it says, yes.

Q. And it was the Vyera business decision to block the Daraprim sales data that was the cause of the FDA's concerns?
A. That seems to be the case.
Q. Vyera made the business decision to block the data because it wanted to discourage generic competition to Daraprim?
A. I don't know why they made the business decision.
Q. You never discussed that with Ms. Kirby?
A. I don't believe I did, no.
Q. Or anybody else?
A. Nope.
Q. All right. Thank you.

MR. MEIER: We can take that down, please.

Q. Have you ever heard of a company called Imprimis?
A. Yes.
Q. What is Imprimis?
A. Imprimis is a drug compounding company.
Q. What is compounding in the context of the pharmaceutical business?
A. Drug compounding is when a company like Imprimis, or even a local pharmacy, takes a drug and makes a dosage form for a particular patient that is not an approved dosage form.
Q. Would an example be somebody who has difficulty swallowing a capsule, the pharmacist could turn that into a liquid suspension?
A. Yes.

Q. This would usually done on a patient-by-patient basis?
A. It is supposed to be done on a patient-by-patient basis.
Q. Are compounders subject to the same GMP quality regulations that a pharmaceutical company like Vyera is?
A. No, they are not.
Q. So they don't have to meet the same quality standards that Vyera would have to meet?
A. That's correct.
Q. Do compounding pharmacies have to make application to the FDA for review to get approval?
A. No, they do not.
Q. In your mind, does that create safety concerns with compounding pharmaceuticals?
A. In my mind, it's a potential to create a safety concern.
Q. Because you don't know whether the product has impurities in it or could otherwise have been compromised?
A. That's correct.
Q. You also don't know whether the compounded drug has the right dose of the active pharmaceutical ingredient?
A. That's correct.
MR. MEIER: Ms. Guy, would you please put Government Exhibit 3208 on the screen.
Q. Take a moment to look at that. I am going to actually have Ms. Guy show you the first page too of the letter that's attached. Take a moment.

A. Yup.

MR. MEIER: Ms. Guy, can you show a little bit more of the next -- that's fine. We will show the letter. Put the letter up too.

Q. Do you see that?

A. I do.

Q. Have you seen Government Exhibit 3208 before?

A. Yes, I have.

Q. What is it?

A. It's a letter that Turing wrote to the FDA office of compliance about Imprimis and their practices.

Q. Did you write part of this letter?

A. Yes, I did.

Q. You actually signed this letter, right?

A. That's correct.

MR. MEIER: Your Honor, I'd like to move to admit Government Exhibit 3208 into evidence.

THE COURT: Received.

(Government Exhibit 3208 received in evidence)

Q. Let's look at the first page of your letter to the FDA, which is actually the third page of the exhibit, the page we are on right now.

This is a letter that you sent to the FDA's office of compliance on behalf of Vyera, correct?

A. That's correct.

Q. In it you're basically talking about compounding that was being done by Imprimis, correct?
A. Yes.
Q. And you have included various information about concerns that Vyera has with compounded pyrimethamine.
A. I'm sorry. Say that again.
Q. Let me see what I said.

You have included various information about concerns about Vyera has with compounded pyrimethamine.
A. That's correct.
Q. Did you write the entire letter?
A. I did not.
Q. So some parts of it were written by others?
A. Correct.
Q. Including by a law firm?
A. That's correct.
Q. Again, I am not going to go into those details.

Did you review the letter before you signed it?
A. Yes.
Q. Do you agree with the letter's contents?
A. I do.
Q. Still looking at Government Exhibit 3208 and still looking at the first page, let's go to the statement where it says: Compounded drugs can pose serious health risks for patients. You see that?

A. I do.
Q. Do you believe that to be true?
A. Yes.
Q. The next sentence you say: Compounded drugs are not FDA approved. Do you see that?
A. Yes.
Q. What's the relevance of this?
A. A compounded drug is not an approved drug product. So it is not under the same strict regulatory oversight as an approved drug.
Q. Let's look at the last sentence of this same paragraph, the one that starts with: As a result. Are you with me?
A. Yes.
Q. It says: As a result, it is not appropriate to use a compounded product in lieu of an FDA-approved, commercially available product unless the compounded drug provides a medically necessary and unavailable drug for a specific patient. Do you see that?
A. I do.
Q. What's the concern that you are trying to convey to the FDA there?
A. Again, this is -- these are products that are not approved. They don't have the same oversight. You cannot necessarily guarantee the quality, the purity, and the fact as to whether or not it has got the right dose, as you mentioned before.

Q. Let's turn to page 10 of your letter to the FDA, which is actually page 12 of Government Exhibit 3208. There is a paragraph there in the middle where it says compounding drugs. Do you see that?

A. Yes.

Q. It says: Compounding drugs in the absence of CGMP compliance increased the potential for preparation errors. In addition, the shelf life of compounded drugs is not verified by stability testing, which is required under CGMP, and therefore such products cannot be assumed to retain their strength and purity over time. Do you see that?

A. Yes.

Q. What's the concern if a product can't retain its strength in purity over time?

A. The concern is twofold. It loses its strength. You are not giving the patient the correct dose. So you would underdose if it's losing strength. If the purity isn't maintained, you could be treating the patient with a drug product that has potentially toxic impurities.

Q. Dr. Pelliccione, when you communicate with the FDA in your capacity as Vyera's head of regulatory affairs, you always try to be accurate, correct?

A. Yes.

Q. You don't purposely write anything to the FDA that you know is incorrect or untrue, correct?

A. To the best of my ability.
Q. You have a duty of candor when communicating with the FDA, correct?
A. I don't know what you mean by that.
Q. I'll move on.
When you communicate with the FDA, Dr. Pelliccione, you always try to be honest, correct?
A. Yes.
Q. Thank you, Dr. Pelliccione.
MR. MEIER: Your Honor I pass the witness.
CROSS-EXAMINATION
BY MR. CASEY:
Q. Dr. Pelliccione, I just have some questions to ask you based on your testimony this morning.
First of all, you testified about being hired at Vyera. Who hired you to work at Vyera?
A. Martin Shkreli.
Q. Was Martin Shkreli a participant in the Vyera's relationship with Fukuzyu?
A. No.
Q. I want to go back to the testimony about the meeting in Japan at Fukuzyu. I believe you said it was September of 2016. Do you recall that?
A. October.
Q. October of 2016.

What was the purpose of that meeting?

A. We went to Fukuzyu to talk with them about supplying pyrimethamine API for us. We had had a number of communications by e-mail and there seemed to be some hesitancy on the part of Fukuzyu to agree to have us -- to supply API for us. Specifically, actually, the concerns were over Martin's problems that he was having as of, I guess, September 2015.

So we thought, and it's always good business practice, to visit your partners. And in Japan it's definitely a good thing to do, to visit your partner and establish a relationship with them. So we really went there to present to them what the overall function and strategy of the company was. We were not only selling Daraprim, but that we were looking into other programs on an R&D basis. That was one of the main reasons we went there.

Q. Just so I have the timeline correct, this was in October of 2016, correct?

A. That's when we went, yes.

Q. And the MSA, the agreement between Vyera and Fukuzyu that you were shown this morning, that MSA occurred a couple of months after that, in January of 2017?

A. I believe that's correct, yes.

Q. Was the purpose of the meeting in Japan in October of 2016 to determine whether Fukuzyu was CGMP compliant?

A. No, that wasn't the purpose.

Q. You were asked about a tour that you took of the Fukuzyu facilities. Do you remember that testimony?
A. I do.
Q. Can you tell the Court a little bit more about that tour and what the purpose of that was?
A. Yes. Part of the agenda of the meeting was that we were asked to take a tour. I don't know if we asked specifically, but it was part of the agenda. But the idea was just to see what the plant looked like, to show us their facilities, to get an overall view of what Fukuzyu was all about, because no one from Vyera or Turing at the time had ever been there. It was definitely not a GMP audit.
Q. How long did the tour last?
A. Less than an hour.
Q. Did you consider this tour to be an inspection of the Fukuzyu facility?
A. No, we did not.
Q. Now, after the MSA was entered in January of 2017, did you have an audit performed of Fukuzyu?
A. We did.
Q. Did Vyera conduct that audit?
A. We had a third party auditor do it for us.
Q. Do you remember approximately when that audit took place?
A. Off the top of my head, no.
Q. Do you know if the audit took place after the MSA was

entered in January of 2017?
A. I believe it was.
Q. Now, you were also asked about a QA agreement, quality agreement?
A. A quality agreement, yes.
MR. CASEY: Can we have DX-444 put up, Justin.
Q. Dr. Pelliccione, I am showing you, you can see on the screen there Exhibit DX-444. Do you recognize that?
A. Yes.
Q. Is that the quality agreement that Vyera and Fukuzyu agreed to on January 27 of 2017?
A. Yes.
Q. The quality agreement was a separate agreement from the MSA, correct?
A. That's correct.
Q. There were two agreements entered at roughly the same time in January of 2017, correct?
A. Yes.
Q. Is it required that the quality agreement be entered or agreed upon on the same day or around the same time as the MSA?
A. I don't believe so, no.
Q. You were asked about another product that Vyera makes called Vecamyl. Do you remember that testimony?
A. Yes.
Q. Who provides the API for Vecamyl?

A. Currently, no one. But in the past it was a company called AMRI.

Q. Does Vyera have a contract with AMRI to provide API?

A. No. Vyera actually does not own that ANDA. It's owned by another company.

Q. You were asked about the exclusivity provision in the contract between Vyera and Fukuzyu. Do you remember that?

A. Yes.

Q. Was the fact that generic manufacturers could not buy pyrimethamine the reason that Vyera requested exclusivity from Fukuzyu?

A. I don't believe that that was the sole reason, no.

Q. I'm sorry?

A. I don't believe that that was the main reason, no.

Q. I want to go back to two exhibits you were shown this morning. The first is GX-1003.

MR. CASEY: Can we get that.

Q. Mr. Meier asked you questions about this document.

MR. CASEY: Could you go to the bottom of the document, the first in time e-mail.

Q. This is an e-mail from Mikio Arisawa to you on May 15, 2018. The subject is: Need your quick response. Correct?

A. That's correct.

Q. It was Mr. Arisawa that initiated this question to you, not Vyera initiating the question, correct?

A. That's correct.
Q. What did you understand the reason was for Mr. Arisawa to ask you this question?
A. He wanted to know whether or not this company was a Vyera-related company.
Q. What was your understanding as to why he wanted to know whether the company was a Vyera-related company?
A. I am not sure I know what the specific reason was at that point.
Q. Was it Vyera that was concerned about compliance with the contract or was it Fukuzyu that was approaching Vyera having concerns about compliance with the contract?
A. It was Fukuzyu approaching us to find out whether or not they were in compliance.
MR. CASEY: Could we go to 1005, please. Again, if you could go to the bottom. Yes. Thank you.
Q. The first e-mail in time there is Tuesday, November 28, 2017 to you. That's from Mr. Arisawa, correct?
A. Yes.
Q. I think it's on the next page where it's from.
A. Yes.
Q. Again, this was another circumstance where Fukuzyu was initiating the question to Vyera about compliance with the contract, not the other way around, correct?
A. That is correct.

MR. CASEY: You can take that down, Justin. Thank you.

Q. You were asked this morning about DMFs, drug master file. Do you remember that testimony?

A. Yes, I do.

Q. Does a pharmaceutical manufacturer need to partner with an API supplier with a DMF like Fukuzyu?

A. No.

Q. What are the other options if the supplier does not have a DMF?

A. The other option is to manufacture or have the manufacturer of the API and the whole process included in what's known as module 3 of the NDA, where all the CMC information is provided.

Q. Now, you were asked also about a second or backup supplier. Do you remember that testimony?

A. Yes.

Q. Do you consider a contract with a backup supplier something that is good to have?

A. It's a good to have.

Q. Can you explain why.

A. In the event that you have no supply, such as we currently have in the case of Vecamyl, if you have a backup supplier, you can bring them along and continue -- and keep your supply chain constant.

Q. Can you explain for the Court just what you are speaking

about with the Vecamyl situation in a little bit more detail.

A. Before you asked me who the API supplier was, and AMRI was the API supplier for mecamylamine, which is the API for Vecamyl. They stopped making the API and we are distributing that product. It's a very small distribution, very small patient population. But it's a pretty critical drug for the patients that use it, so we want to keep that drug on the market.

So we talked about LGM, who is now the owner of the ANDA for Vecamyl and asked if they were going to pursue -- or if we could pursue finding a new API supplier, and they agreed. So we went out and found a company that will manufacture the API for Vecamyl.

Q. What company is that?

A. That's Piramal.

Q. I think you testified you do not currently have a contract to produce API with Piramal, correct?

A. We do have a contract with Piramal. We don't have a contract with AMRI.

Q. At the time of the contract with Piramal, did Vyera also have a quality agreement with Piramal?

A. We have not finalized the quality agreement.

Q. Thank you.

In terms of why a backup supplier is helpful, what would be the result if you ran out of API or if your supplier

couldn't supply it, as in the case of Vecamyl? What's the result of that?

A. You would wind up not being able to manufacture any more drug product, and ultimately you would have a drug shortage.

Q. When Mr. Meier was asking questions about your negotiations with Fukuzyu, I believe you testified that you had offered to Fukuzyu to buy other API other than the pyrimethamine API, is that correct?

A. Actually, we offered that we would want to work with them to manufacture API for new products that we were working on; in other words, new compounds that we were working on in the company through R&D. We didn't have manufacturers specifically for them. So we wanted -- we asked Fukuzyu if they might be interested in manufacturing API.

Q. Can you explain for the Court some of those projects that you were seeking or offering API for.

A. The one I remember best is what we now refer to as VYR006. That is a compound developed for the treatment of toxoplasmosis. It was developed by Vyera. It's the same mechanism of action as Daraprim, but has different properties, much more specificity. So we were looking to take that product forward as a new treatment for toxoplasmosis.

Q. Are there any other projects that you were working on at the time you were negotiating with Fukuzyu?

A. They are not jumping into my mind right now. We were

working on Stiripentol, which was another investigational agent we were working on. I don't recall if that was one of the products that we asked them about.

MR. CASEY: Your Honor, I neglected to move into evidence document DX-444. Defendant would move into evidence DX-444.

THE COURT: Received.

(Defendant's Exhibit 444 received in evidence)

MR. CASEY: I have no further questions for the witness, your Honor. Thank you.

THE COURT: Anything further?

MR. MEIER: Very briefly, your Honor.

REDIRECT EXAMINATION

BY MR. MEIER:

Q. Dr. Pelliccione, a moment ago you mentioned a project that Vyera had been working on that was labeled VYR006. Do you recall that?

A. Yes.

Q. That project has effectively been shelved since approximately October of 2018, correct?

A. More or less, yes.

Q. In the seven years or so that you've been at Vyera, has Vyera ever successfully launched any new product?

A. No.

MR. MEIER: No further questions, your Honor.

THE COURT: Just give me one second, sir. Thank you.

This new treatment for toxoplasmosis that you referred to, that was going to use the same API pyrimethamine or a different API?

THE WITNESS: No. It's a completely new chemical entity.

THE COURT: So when you were in discussions with Fukuzyu, you were discussing working with them to be the manufacturer of a new API for a new product?

THE WITNESS: That was what we were discussing, yes.

THE COURT: That was part of the October 2016 discussions in Japan?

THE WITNESS: That was part of the presentation, yes.

THE COURT: Was it your impression that that opportunity had some significance in Fukuzyu's decision making about the contract or MSA that you entered into with them? Did they seem interested in that?

THE WITNESS: They were interested, yes.

THE COURT: That's the only additional question I have.

Did my question suggest any additional questions for you, Mr. Meier?

MR. MEIER: No, your Honor. Thank you.

THE COURT: Mr. Casey.

MR. CASEY: No, your Honor.

THE COURT: You may step down. Thank you.

THE WITNESS: Thank you.

(Witness excused)

THE COURT: Give me one second, counsel.

Next witness.

MR. MEIER: Thank you, your Honor.

Unfortunately, as chance would have it, you have would hear from me again. I promise the Court that after today you will be hearing from a lot of my colleagues here.

The government calls as its next witness Dr. Eliseo Salinas.

THE COURT: Is someone getting Dr. Salinas?

Dr. Salinas, thank you.

Please take the witness stand. Remain standing.

ELISEO ORESTE SALINAS,

called as a witness by the Plaintiffs,

having been duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. MEIER:

Q. Good afternoon, Dr. Salinas.

A. Good afternoon.

Q. We have never met before, but you have met some of my FTC colleagues at your investigational hearing in September of 2019 and at your deposition earlier this year.

Just so you know, my name is Markus Meier, and I'm

with the Federal Trade Commission.

A. Nice to meet you.

Q. Is there anything that might affect your ability to give truthful, complete testimony today?

A. No.

Q. Just so you know, Dr. Salinas, you may hear from time to time I'll make reference to Ms. Guy, and that's the paralegal that's assisting me, and hopefully the courtroom technology will work and we will be able to pull up some exhibits for you to look at.

Dr. Salinas, I'd like to start by talking briefly about your background and experience in the pharmaceutical industry.

You joined Turing in June of 2015 as the president and head of research and development, correct?

A. Correct.

Q. Turing is now called Vyera.

A. Yes.

Q. In fact, the name changed from Turing to Vyera while you were still at the company, correct?

A. I believe so.

Q. And the company changed its name in the hope of distancing itself in the public eye from Martin Shkreli, correct?

A. Correct.

Q. For the purposes of remainder of my examination, when I

refer to Vyera, I also mean the company formerly known as Turing. Do you understand that?

A. I do.

Q. As president and head of research and development, you were part of Vyera's senior leadership team?

A. Yes.

Q. And you were also Vyera's interim chief executive officer between April 2017 and July 2017?

A. Yes.

Q. So you worked for Vyera a little more than two years?

A. Yes.

Q. Just to bookend those dates, you worked at Vyera before it purchased the rights to Daraprim, and you left shortly before a jury found Mr. Shkreli guilty of securities fraud, correct?

A. Correct.

Q. Do you have a medical degree?

A. I do.

Q. You specialize in psychiatry and pharmacology?

A. Correct.

Q. Pharmacology is the study of how drugs work in the body?

A. Yes.

Q. You are still a practicing physician?

A. No.

Q. You're mostly a research scientist?

A. Yes.

Q. And you have worked in the pharmaceutical industry for about 30 years?
A. Over 30 years.
Q. Over. Thank you.
You've primarily worked in the areas of pharmaceutical research and development, correct?
A. Correct.
Q. When you first started working at Vyera, you reported to Martin Shkreli?
A. Yes.
Q. And Mr. Shkreli was the chief executive officer at the time?
A. Yes.
Q. And is it correct that Mr. Shkreli personally recruited and hired you?
A. Yes.
Q. And you met with Mr. Shkreli as part of the interview process when you were considering taking the job?
A. I did.
Q. And Mr. Shkreli interviewed you.
A. He did.
Q. When you and Mr. Shkreli both worked at Vyera, you would meet periodically with Mr. Shkreli?
A. Very often.
Q. Could give me approximately how frequently? Are we talking

about daily, weekly?
A. At least weekly.
Q. When you and Mr. Shkreli both worked at Vyera, you would speak with him periodically, even if you didn't meet with him, correct?
A. Yes.
Q. Can you give us approximately how frequently did you speak with Mr. Shkreli?
A. It was weekly. Most of our interactions were one on one, person to person, weekly.
Q. You said most of the time when you had your weekly meetings, it would just be you and Mr. Shkreli?
A. Correct. There were also meetings with the rest of the executive team and other people in the company. But because of my position, I had weekly interactions, one on one with him.
Q. Weekly interaction one on one was in addition to senior leadership team meetings?
A. Yes.
Q. When you and Mr. Shkreli both worked at Vyera, you exchanged e-mails with each other?
A. Yes. Not many. My recollection is that most of our contacts were those weekly one-on-one interactions.
Q. Did you ever hear Mr. Shkreli talk about the business model he used at a pharmaceutical company called Retrophin before he started Vyera?

A. Not specifically. He had -- I knew he was in conflict with his previous company and the topic of his previous company did not come up often in my discussion with him.

Q. In any of your meetings leading up to you joining Vyera or after Vyera, did Mr. Shkreli ever explain to you Vyera's business model?

A. Yes.

Q. Do you recall hearing Mr. Shkreli describe the business model in the following way? First, you try to identify drugs that are the gold standard of care, that you like to look for drugs that are the gold standard of care. Is that something that Mr. Shkreli discussed with you?

A. No.

Q. Did he ever talk to you about looking for drugs that have a small patient population?

A. No.

Q. Do you ever recall Mr. Shkreli saying that you try to acquire the drug that only has one manufacturer?

A. No.

Q. Or that has no immediate generic competition?

A. No.

Q. Did you ever hear Mr. Shkreli talk about the business model that you tried to control access to the drug through a closed distribution system?

A. No.

Q. Even if you never heard Mr. Shkreli say anything about a closed distribution system, did you see him do this with Daraprim?
A. Yes.
Q. Even though you never heard Mr. Shkreli describe the business model that you look for drugs that serve a small patient population, did you see Mr. Shkreli actually do that?
A. Not uniquely.
Q. What do you mean by that?
A. We had -- Turing had a number of research programs, some of them in very large indications, like depression, for example, which is a very large indication. Others were aware. But the business model was not presented with focusing on rare diseases. I have worked in other companies that do focus on rare diseases, but it was not presented to me as such.
Q. Thank you.

Do you ever recall hearing Mr. Shkreli describe the business model with words to the effect that you raise the price of the drug significantly to maximize profits?
A. Only after the acquisition of Daraprim explaining his decision.
Q. Even if you never heard Mr. Shkreli say that this was part of the business model, you actually saw them do this with Daraprim, correct?
A. I saw him doing this with Daraprim, yes.

Q. During the time you worked at Vyera, almost all of the companies' revenues came from the sales of Daraprim, correct?
A. No, not exactly.
Q. Where did they come from?
A. There were two periods in the company, before and after Daraprim. I joined the company before the acquisition of Daraprim, when the company had raised almost like 60 or $70 million in investor funds. That was the business model then, raising money from investors. He did present the acquisition of marketed products at the end of their commercial life as a way of getting additional revenue so we wouldn't have to go too often and raise money from investors. He had done that with Vecamyl, who was an acquisition with a very small patient population that would bring additional revenues to the company. But when I was hired, the main source of income of the company was the money from investors.
Q. Thank you for that clarification.

I want to focus on just the period after Daraprim was acquired. Do you follow that?
A. I do.
Q. In the period after Daraprim was acquired by Vyera, would it be fair to say that almost all the companies' revenues came from the sales of Daraprim?
A. Yes.
Q. In that same period after acquisition of Daraprim, almost

all the company's profits came from the sales of Daraprim?
A. Yes.
Q. After that period your salary at Vyera came mostly from the sales of Daraprim?
A. Presumably, yes.
Q. What was your highest annual salary when you worked at Vyera?
A. I believe it was $600,000.
Q. That was back in 2017 or 2016?
A. No. That would have been when I was hired. I was hired with that salary.
Q. In addition to your salary, you typically received a bonus?
A. Yes. Well, I did not. But the idea was that I would.
Q. So did you ever receive a bonus?
A. I don't think so, no. I am not sure about that. I don't think so, but I'm not positively sure.
Q. Would it be fair to say that as the chief scientist and being familiar with the research and development pipeline of the company in 2017, that you believe that Vyera would need to continue to rely almost exclusively on Daraprim revenue for at least two to four more years?
A. It was my hope that would not be the case.
Q. You thought that it might be, depending on how well the research and development projects went?
A. And how well we could attract additional investors or the

regional investors to continue supporting the company.
Q. Again, putting yourself back into 2017, during that time period, you believed, though, that it was possible that in order for Vyera to continue it would need to rely on revenues from Daraprim sales for anywhere from two to four years?
A. Yes.
Q. You worked at Vyera when Mr. Shkreli raised price of Daraprim by 4,000 percent?
A. I don't recall if it was exactly 4,000 percent, but it was an enormous increase, yes.
Q. Did you ever hear Mr. Shkreli say words to the effect that he should have raised the price of Daraprim even higher?
A. I don't recall that. But I would have not been surprised by him saying that.
Q. Did you ever hear Mr. Shkreli say words to the effect that, I could have raised the price of Daraprim even higher and made more profits for our shareholders?
A. I don't recall exactly, no.
Q. While working at Vyera, you were a shareholder in the parent company Phoenixus, correct?
A. I received shares as part of my compensation, so, yes, technically, yeah, I was a shareholder.
Q. In March of 2017, you owned about 20,000 shares of Phoenixus?
A. It sounds right, but I don't recall the details.

Q. Did you hold the voting rights to those shares?
A. Yes, I did.
Q. Did Mr. Shkreli hold the voting rights to any of your shares?
A. No.
Q. It was Mr. Shkreli that made the decision to increase the list price of Daraprim to $750 a tablet, right?
A. Yes.
Q. And you've called that Daraprim price increase "excessive."
A. I did.
Q. You have called that Daraprim price increase "crazy."
A. I did.
Q. And you have called that Daraprim price increase "irresponsible."
A. I did.
Q. And you have called that Daraprim price increase "careless"?
A. I did.
Q. And you have called that price increase the poster child of everything that is considered wrong about the pharmaceutical industry, correct?
A. Correct.
Q. Let's shift gears and talk a little bit about Daraprim, the product. It was first approved by the FDA in 1953?
A. Correct.

Q. It's used to treat toxoplasmosis?
A. It is.
Q. And toxoplasmosis is a potentially serious parasitic infection?
A. Yes.
Q. Is Daraprim considered the gold standard treatment for toxoplasmosis?
A. Not everywhere, but some people do consider it the gold standard.
Q. Do you consider it to be the gold standard treatment for toxoplasmosis?
A. I do.
Q. Did you ever hear Mr. Shkreli refer to Daraprim as the gold standard treatment for toxoplasmosis?
A. I don't recall.
Q. Have you ever heard of a product called Bactrim?
A. I did.
Q. What is Bactrim?
A. Bactrim is another antibiotic. It's a combination product that acts on a number of infections, including toxoplasmosis.
Q. Do you believe that Bactrim is medically inferior to Daraprim for the treatment of toxoplasmosis?
A. I do.
Q. You believe Bactrim is medically inferior to Daraprim because not enough of the drug reaches the brain or the retina,

which are key areas of active toxoplasmosis infection?
A. I do.
Q. The generic version of Bactrim is also known as TMP-SMX?
A. Correct. That's the two drugs, abbreviation of the two drugs that made the combination called Bactrim.
Q. I can't pronounce those, so I am not going to try.
You believe that TMP-SMX also is medically inferior to Daraprim for the treatment of toxoplasmosis?
A. I do.
Q. Do you believe that compounded pyrimethamine products can pose safety concerns for patients?
A. It depends how they are compounded.
Q. Do you also believe that compounded pyrimethamine is medically inferior to Daraprim for the treatment of toxoplasmosis?
A. No, I don't.
Q. Thank you.
MR. MEIER: Ms. Guy, would you please put Government Exhibit 1075 on the screen.
Q. The way this is going to work, we will put the document on the screen, have you just take a look to see whether you are familiar with it. I am going to ask you, have you seen it before and what is it? Then we will go through it.
A. OK.
Q. Let me first ask, have you seen Government Exhibit 1075

before?
A. Yes, I have. Can I move the screen a little bit?
Q. Hopefully without a plug falling out. If you need to see it better.
A. That's OK. Thank you.
Q. Perfect.
Have you seen the e-mail that's been marked as Government Exhibit 1075 before?
A. I have.
MR. MEIER: Could we quickly look at the second page of the exhibit, which is the first page of a letter.
Q. Do you see that letter there?
A. I do.
Q. Have you seen that before?
A. I have.
Q. What is the letter?
A. It's a letter I wrote to the directory of two medical associations alerting them about what a compounding group was doing.
MR. MEIER: So at this point, your Honor, I would move to have Government Exhibit 1075 admitted.
THE COURT: Received.
(Government Exhibit 1075 received in evidence)
Q. So we are looking at the letter now, which starts on the second page of the exhibit. And, again, you wrote this letter,

correct?
A. I did.
Q. Looking at the top of the first page of the letter, you sent this letter to actually three different doctors, correct?
A. Correct.
Q. One of the doctors is a Dr. Bakken, correct?
A. Yes.
Q. That was to Dr. Bakken in his capacity as the president of an organization known as IDSA.
A. Correct.
Q. IDSA stands for the Infectious Disease Society of America.
A. Yes.
Q. The next recipient is Carlos Del Rio, who is the chair of HIVMA, correct?
A. Correct.
Q. And HIVMA is the HIV Medical Association.
A. Yes.
Q. The third person is Janet Gilsdorf, Dr. Gilsdorf, who is the president of FPIDS and PIDS, correct?
A. Correct.
Q. And PIDS stands for Pediatric Infectious Disease Society?
A. Yes.
Q. Would it be fair to say that these three organizations represent the physicians most likely to treat patients with toxoplasmosis?

A. The one left out would be the ophthalmologist that is in fact the most common form. But these would represent the ones that treat toxoplasmosis encephalitis associated with the HIV infection.

Q. Toxoplasmosis encephalitis is the toxoplasmosis in your brain?

A. Correct.

Q. As opposed to ocular, which is in your eye?

A. Yes.

Q. These three organizations are the ones that represent the physicians most likely to treat patients with toxoplasmosis encephalitis?

A. In general, yes.

Q. These three organizations represent the physicians most likely to prescribe Daraprim for toxoplasmosis encephalitis?

A. Yes.

Q. If we could just turn very quickly to page 4 of the letter. I just want to ask you if that is your signature.

A. It is.

MR. MEIER: We are going to go back to the first page and the first sentence. Ms. Guy is going to blow that up so we can see this a little bit better.

Q. Do you see where it says I am writing?

A. I do.

Q. It says: I am writing to you today to call to your

attention our concerns regarding your endorsement of the partnership between Imprimis Pharmaceuticals and Express Scripts to make available a new unapproved drug combination for the treatment of toxoplasmosis. Do you see that?

A. I do.

Q. In this letter you're letting the heads of the nation's leading infectious disease organizations know that Vyera doesn't believe that Imprimis' compounded pyrimethamine product is an acceptable substitute for Daraprim, correct?

A. No. I didn't believe that. I don't know if Vyera believed or not. I didn't believe that. Yeah. I know that they were in agreement with me, but that was my belief.

Q. But you're sending this on behalf of Turing, correct?

A. Correct.

Q. You sent this on Turing letterhead?

A. Yes.

Q. You sent it in your capacity as the top science person at Turing?

A. Correct.

Q. This was not a personal letter you were sending?

A. No. I meant to say that these represent my views. Someone in the company asked me to write a letter, and I wrote a letter.

Q. You had the authority to send this letter?

A. Correct.

Q. Let's turn to page 2 and there is a bolded heading there that says "promoting an unapproved drug." Do you see that?
A. I do.
Q. Let me see it myself here.
A. Can I make a clarification?
Q. If you need to.
A. You asked me before if I thought that a compounded product was inferior, and I said no. But these refer to a type of compounding that is not the typical compounding. This is the first to the compounding that is done before a patient comes with a medical need. The compounding that is done, a priority. That was the essence of my letter.
Q. So if I understand that clarification, you're drawing a distinction between the type of compounding Imprimis is doing and the kind of compounding a doctor might request for a specific patient who needs a specific compounded drug because of some specific condition they had, like difficulty swallowing?
A. Correct. That would not be, in my opinion, inferior. This was, in my opinion.
Q. Sort of mask compounding, if you will, sort of mask producing compounded product, correct?
A. Yes.
Q. I appreciate that distinction.
What are you trying to convey to the three heads of

the largest infectious disease organizations in America in this paragraph here where you're talking about promoting an unapproved drug?

A. My belief was that they underestimate the negative consequences of what Imprimis was doing. I believe that they were honestly concerned about patient safety and access to drugs. But because probably they were not familiar with the details of compounding, they underestimated certain aspects that, in my opinion, were important to consider.

Q. What would some of those aspects be that you thought were important to be considered?

A. One is the fact that compounding done this way is not regulated by the FDA. That's one.

The second was that that is a fixed dose compounded in many cases because they were compounding Daraprim with Leucovorin, which is another medication you could take with Daraprim. And because it was, to use your term, it was mask compounding. They were using a fixed combination.

My recollection is, there were at least two risks. One was the fact that the combination, flexible dosing of one and the other component were not contemplated and, two, that a drug for a life-threatening disorder would be manufactured outside the regulatory purview of the FDA.

Q. If I understood correctly, to put it in my nontechnical terms, you were concerned that Imprimis was sort of making a

one-size-fits-all form of Daraprim and Leucovorin and individual patients actually need different balances of that?

A. Yes.

Q. That could create medical issues for the patient?

A. Yes.

Q. And safety issues?

A. Yes.

Q. That's what you are trying to convey here to these heads of these various infectious disease organizations?

A. Yes. Along with the regulatory aspect that is not an approved drug. My recollection is I was focusing on the medical aspects of the problem beyond the legal one.

Q. Understood. In fact, to pick up on that point, the FDA has made no finding that Imprimis' compounded product as safe or effective in treating toxoplasmosis, correct?

A. Correct.

Q. Let's move to another part of page 2 of your letter. There is a bolded heading that says unsafe manufacture. Do you see that?

A. I do.

Q. Would it be fair to say that in the part about unsafe manufacturing you're pointing out that Imprimis' manufacturing facilities have been cited by the FDA for violations of current good manufacturing practices?

A. Yes.

Q. Let's go to page 3, the third paragraph, which is still talking about unsafe manufacturing. You write: Compounding drugs in the absence of CGMP compliance increases the potential for errors in manufacturing the product. In addition, the shelf life of compounded products is not verified by stability testing, which is required under CGMP, and therefore such products cannot be assumed to retain their strength and purity over time. Do you see that?

A. I do.

Q. Why is that?

A. Excuse me. Why is what?

Q. Why is this true? What are you trying to convey here?

A. The pharmaceutical business is the most heavily regulated business, and it should be that way with life-saving medications or medications that can put patients at risk if they are not appropriately controlled. In my 30 years in industry I have seen an increase, a tightening of the regulations. As a consumer and a patient, I think that's a good thing. That's a good thing.

The lack of oversight in the manufacturing of a life-saving medication struck me as something that was not right.

Q. Is there a risk to patients' health from compounded pyrimethamine, potentially?

A. Well, for example, if the doze of Leucovorin is

inappropriate, yes, there are serious consequences that can arise from that.

Q. What's the risk to a patient's health if a product such as compounded pyrimethamine doesn't retrain its strength and purity?

A. Two. Number one, but might not be as effective, treat the underlying condition and, number two, is that it can pose safety risks. The mechanism of action of Daraprim is to inhibit, to block the activity of an enzyme called DGHR, which is necessary for the parasite, but also for the patient. That's why Leucovorin is given, so that the blocking of that enzyme kills the parasite, but not the patient. So having an inadequate dose of Leucovorin could represent serial risks for the patient.

Q. Thank you.

MR. MEIER: Ms. Guy, you can take Government Exhibit 1075 down.

Q. Let's talk about your role in Vyera's efforts to enter into an exclusive supply agreement with the Japanese API supplier called Fukuzyu.

My first question is, you were involved in Vyera's efforts to enter into an exclusive API supply agreement with Fukuzyu, correct?

A. Yes.

Q. And Fukuzyu is a Japanese API supplier that had been

producing pyrimethamine since around 1966.
A. I believe so. I don't mean to correct you, but I call it Fukuzyu because that is the way I know it always. I will refer to them that way.
Q. I appreciate that. You've been to Japan. I haven't. But I'm so locked in on Fukuzyu, I am going to keep saying it that way and I apologize.
Fukuzyu held a U.S. drug master file for pyrimethamine API, correct?
A. Correct.
Q. And what is a drug master file or DMF?
A. It's a document that is filed with regulatory authorities that describe the processes and procedures of the manufacturer of API that allowed the regulator to conduct audits.
Q. You personally went on the trip to Japan in 2016 to meet with Fukuzyu?
A. I did.
Q. And you went with two other people from Vyera who worked with you on science, regulatory, and manufacturing issues for Vyera?
A. I did.
Q. And no one from Vyera's business development team visited Fukuzyu in Japan with you in 2016, correct?
A. Correct.
Q. As part of your visit to Japan you toured the plant where

Fukuzyu makes the API?

A. Yes.

Q. And you were part of the team at Vyera that was responsible for getting the agreement with Fukuzyu to supply Vyera with pyrimethamine API, correct?

A. Yes.

Q. It was Vyera that first raised the issue of including an exclusivity provision in the supply agreement with Fukuzyu?

A. I am not sure what you mean by first.

Q. I mean, Fukuzyu didn't say to you: We want that in the contract. You said to them: We want it in the contract?

A. Correct. It was our demand, yes.

Q. It was Vyera that first raised the issue of including exclusivity?

A. Yes.

Q. To the best of your knowledge, would Fukuzyu have been willing to supply Vyera with API for Daraprim even without the exclusivity provision?

A. Yes.

MR. MEIER: Ms. Guy, would you please put up Government Exhibit 1056 on the screen.

Q. Again, Dr. Salinas, I am just going to ask you to take a moment to look at it, get yourself familiar with it.

A. I don't remember this e-mail.

Q. You remember it?

A. Yes.

Q. Let me just ask you, have you seen the e-mail chain marked as Government Exhibit 1056 before?

A. Yeah. I can see the number. The e-mail in the screen, yes, I have seen it.

Q. What is it?

A. It's an exchange between Mikio Arisawa and myself, copied to Nick Pelliccione, where Mikio Arisawa was asking me -- he was preparing for a meeting with Mr. Kosugi, the CEO of Fukuzyu, and Mikio Arisawa was asking me whether the ideas -- he was going to mention were OK or not.

MR. MEIER: Your Honor, at this time I move to admit Government Exhibit 1056 in evidence.

THE COURT: Yes. Received.

(Government Exhibit 1056 received in evidence)

THE COURT: We are going to break for lunch. We will resume at 2:00. Thank you.

(Luncheon recess)

AFTERNOON SESSION

2:05 p.m.

THE COURT: I'm sorry that I am a little late.

Is the witness ready to retake the stand?

MR. MEIER: Yes, your Honor.

THE COURT: Thank you.

Counsel, you may resume.

MR. MEIER: Thank you, your Honor. When we took the lunch recess we were just starting to look at Government Exhibit 1056.

And Ms. Guy has pulled that back up for us. I believe it had just been admitted.

Q. Let me pick up there and ask you, again, Dr. Salinas, just to refresh your recollection by taking a quick look at what's on the screen, and then I'll direct you to some specific passages.

A. I remember this e-mail.

Q. In this time frame, 2016, in this e-mail chain, would it be fair to say that you were advising Mr. Arisawa on negotiation strategy to get Fukuzyu to agree with the agreement that you all eventually entered with Fukuzyu?

A. In broad terms, yes.

Q. In broad terms this includes the discussion about getting the exclusivity provision?

A. Yes.

Q. One of the things you advised Mr. Arisawa to emphasize was that Vyera sought to establish a long-term relationship with Fukuzyu and work together on multiple development projects, correct?

A. It's not in this part of the e-mail which is on the screen, but I remember something along those lines, yes.

Q. Let's take a look at page 2 of Government Exhibit 1056. I am going to point you to bullet point number 4, the one that's got --

A. I'm seeing it now.

Q. Do you see that now?

A. I did a second ago. Now it disappeared again.

Q. Point number 4 says in all caps: Our plans are only possible if we have exclusivity for Fukuzyu's API. Do you see that?

A. No. I see an error message that said input signal not found. Check the video cable and video source. Now black screen.

Now, it's back. I am seeing now the exhibit on the screen.

Q. Let's hope that it will participate and cooperate the rest of the afternoon.

It says in all caps: Our plans are only possible if we have exclusivity for Fukuzyu's API. Do you see that?

A. I do.

Q. Do you recall that this is actually a sentence that you wrote?

A. Yes. I believe in the first part of the e-mail I said -- I added my comments in capital letters. This is in all capitals. I remember the concept.

Q. Just to reset the situation, the situation at this point is, Vyera and Fukuzyu have not entered the master services agreement yet but are in negotiations of that agreement.

A. Yes. My group discovered in early 2016 that there was no supply agreement with anybody, and we were very concerned about that because our plans, our research plans and our commercial plans for Daraprim --

THE COURT: Excuse me one second.

Mr. Zach, is that you back there?

MR. ZACH: It is, your Honor.

THE COURT: I will ask my law clerk to get Mr. Whertvine.

So sorry to interrupt. I have a 30-second piece of business I need to do.

(Recess)

THE COURT: Resuming.

Q. Dr. Salinas, we were just starting to look at the content of Government Exhibit 1056, and we were looking at this provision number 4 which says: Our plans are only possible if we have exclusivity for Fukuzyu's API.

I believe you testified that that is a sentence you wrote because you wrote the sentences in all caps, correct?

A. Correct.

Q. Other parts of this page that we are looking at, they were actually written by Mr. Arisawa?

A. Yes, I believe -- yes.

Q. In some places Mr. Arisawa puts something in parenthesis in order to indicate that he wasn't a hundred percent sure whether you wanted him to make that point or not when he spoke with Fukuzyu, correct?

A. Correct.

Q. Number 6 is one of these provisions in parenthesis and it says: If generic products are put on the U.S. market, Turing will face a serious problem, and may eventually terminate the marketing of Daraprim, as well as R&D in toxoplasmosis. Do you see that?

A. I do.

Q. Mr. Arisawa was looking for your guidance on whether he should raise this point with Fukuzyu, correct?

A. Correct.

Q. Do you remember whether you told him he should or he shouldn't?

A. I don't remember. But in the first part of the e-mail I indicate which were the bullet points that, in my opinion, he should retain.

Q. That he should in fact say, meaning he should say that to Fukuzyu?
A. Yes.
Q. Number 6 is one of those points, correct?
A. I don't recall if the brand -- I don't recall if I retained 6 or not in the first part of the e-mail.
MR. MEIER: What we will do is, we will go back to page 1 and take a quick look at that, Ms. Guy. Upper half of the e-mail.
A. I see here. You can retain 6, 9, and 11. So -- I thought 6 was pertinent.
Q. You're telling Mr. Arisawa, regarding your questions, I think you can mention points 6, 9, 10, and 11, correct?
A. Correct.
MR. MEIER: Let's go back and look at 6 on page 2. Sorry for the jumping around.
Q. Number 6 is one you said: Yes, Mr. Arisawa. You can make this point with Fukuzyu.
A. Correct.
Q. You wanted to make this point with Fukuzyu because you wanted to make clear that Vyera didn't want generic competition to Daraprim, correct?
A. No.
Q. That's not correct?
A. That's not correct.

Q. Let's look at the top of page 2. Do you see where it says, in summary, we propose a long-term relationship covering all products in our existing pipeline? Do you see that?
A. It's not showing on the screen. It's showing development in early 2018 --
Q. I'm sorry. I was reading the second sentence, the one that starts at the very end of the first line where it states, with in.
A. Yes.
Q. Let me try that again. In summary, we propose a long-term relationship covering all products in our existing pipeline. Do you see that?
A. I do, yes.
Q. That, again, all caps, indicating that you had typed this in?
A. Correct.
Q. This is the proposal you were having Mr. Arisawa raise with Fukuzyu?
A. Correct.
Q. You wanted Mr. Arisawa to tell Fukuzyu that you wanted to have a long-term relationship with them?
A. Yes.
Q. That was in order to make it interesting for Fukuzyu to contract with you, correct?
A. Not only that. I knew, because of my work in Japan, that

Japanese companies are interested in very long-term relationships and they don't like to engage for short term. On the one hand, it was good for us because it was secure access to the product and other products in our research pipeline, and I knew it would be interesting for them.

THE COURT: Dr. Salinas, I think the answer to the last question could have been the word yes.

If you can answer a question fairly with a yes or a no, you should do that. Only when you can't answer fairly with a yes or a no should you add. Thank you.

MR. MEIER: Thank you, your Honor.

Q. Let me go back to the question then the way I asked it because you said not only that was the first part of your answer. I'll ask the question again. By proposing a long-term relationship, Vyera hoped that Fukuzyu would see -- I'm reading from the wrong place. Now I have lost my place. I apologize.

You intended for Vyera's promise of a long-term relationship on other products to be an appealing offer to Fukuzyu?

A. Yes.

Q. By proposing a long-term relationship Vyera hoped that Fukuzyu would see the benefit of entering into an exclusive agreement with Vyera?

A. An agreement that would include exclusivity.

Q. Thank you.

MR. MEIER: Ms. Guy, we can take that down.

Ms. Guy, would you please put up Government Exhibit 1223.

Q. Again, Dr. Salinas, if you could just try to take a look at this. I'm actually going to focus you on the next page.

MR. MEIER: Let's actually turn to the next page first. Turn to page 2. And about a third of the way down. Thank you.

Q. Do you see that?

A. I do.

Q. So this is part of an e-mail exchange between you and Mr. Arisawa, correct?

A. Yes.

Q. Cc'g Dr. Pelliccione.

A. Yes.

Q. And the subject is exclusivity right was obtained.

A. Yes.

Q. Have you seen this e-mail before?

A. Yes. I remember seeing that e-mail.

MR. MEIER: Your Honor, I would move to admit Government Exhibit 1223 in evidence.

THE COURT: Received.

(Government Exhibit 1223 received in evidence)

Q. Let's actually start by looking at the earliest e-mail in the chain, which starts at the bottom of page 2, and it's from

Mr. Arisawa to you on November 2, 2016 at 4:10 a.m. Are you with me? Are you there, Doctor?

A. Yes.

Q. It's a big paragraph, so I'll try to read it slowly.

In the first sentence Mr. Arisawa writes to you: I have just finished the discussion with Mr. Kosugi. He agreed to give us the exclusivity, in quotation marks, of pyrimethamine for the U.S. The reason why he did not accept our exclusivity request was based on the fact that Fukuzyu is currently selling pyrimethamine to Pegasus, a company that produces drugs for horses. So theoretically he thinks he cannot use the word exclusivity. I asked if he is willing to sell pyrimethamine to generic companies. The answer is no. I stressed that Turing plans to develop four more new compounds and would like Fukuzyu to work together. Also said was the regular purchase of 50 kilogram every year. He appreciated the comments and looked happy. Do you see that?

A. I do.

Q. Again, Mr. Kosugi, he was the top person at Fukuzyu at the time?

A. Yes.

Q. Then at the very end Mr. Arisawa writes: In conclusion, you will get the exclusivity right of pyrimethamine for your territories. Do you see that?

A. I do.

Q. You were happy that Fukuzyu agreed to give Vyera an exclusive API supply agreement, correct?

A. I was happy they could give us a supply, and I was happy it was exclusive, yes.

Q. Thank you.

MR. MEIER: We can pull that down, please.

At this time I would like you to put up Government Exhibit 1484 on the screen. If we could blow that up. Thank you. Include Dr. Salinas' signature block. Not signature block, but his identification. Thank you.

Q. Can you read that, Dr. Salinas, or is it a little bit cut off on the left side?

A. I can. Are you asking me to read it out loud.

Q. No. Just like I've been doing, I'm going to ask, have you seen this before, and what is it?

First, have you seen the e-mail marked as Government Exhibit 1484 before?

A. I vaguely remember it, yes.

Q. What is it?

A. It's me informing the then CEO, Ron Tilles, that Fukuzyu was OK signing an agreement and that we were going to do that imminently.

MR. MEIER: Your Honor, at this time I would move to admit Government Exhibit 1484 in evidence.

THE COURT: Received.

(Government Exhibit 1484 received in evidence)

Q. In the top of the first part of it, after you say hi, you write to Vyera's then CEO, Mr. Tilles: "Just got a call from Mikio that Kosugi-SAN is very happy with the agreement. In particular, the possibility to provide API for our pipeline." Do you see that.

A. I do.

Q. You're reporting to Mr. Tilles, who was the CEO at the time?

A. Yes.

Q. And agreement in that sentence means the master services agreement that includes the provision for Fukuzyu to provide pyrimethamine API exclusively to Vyera for human use in the United States?

A. Including that and other sections.

Q. Understood.

So the possibility to provide API for our pipeline, that's a reference to the fact that as part of the negotiations with Fukuzyu, Vyera offered the possibility of ordering other APIs from Fukuzyu in return for the exclusivity provision, correct?

A. Not exactly. I think it was --

THE COURT: That's fine then. You have answered not exactly.

THE WITNESS: Sorry. I'm confused.

THE COURT: You said not exactly. That's an answer. Thank you.

MR. MEIER: We can take that exhibit down, Ms. Guy.

Q. As part of the negotiations and agreement between Vyera and Fukuzyu, Vyera did not invest any capital in Fukuzyu's manufacturing process for pyrimethamine API, correct?

A. To my knowledge at the time I was there, no.

Q. And Vyera did not pay for Fukuzyu to expand its capacity to make pyrimethamine, correct?

A. I don't know what Fukuzyu did with the monies that were paid, but there was no request, a specific request for expanding capacity.

Q. And Vyera didn't provide Fukuzyu with any technical knowhow to develop the manufacturing process for pyrimethamine, correct?

A. Correct.

Q. Because Fukuzyu already knew how to make it, correct?

A. Correct.

Q. And Vyera didn't share any intellectual property with Fukuzyu as part of the contract, correct?

A. Not about pyrimethamine.

Q. Are you familiar with the Indian company called RL Fine?

A. Yes.

Q. What do you remember about RL Fine?

A. What I remember is that when we were looking for a supplier

of API, RL Fine was one of the potential suppliers if we were not able to establish a relationship with Fukuzyu.

Q. Other than Fukuzyu and RL Fine, do you remember any other API suppliers of pyrimethamine that you were considering back in 2016, 2017?

A. We were looking at all the possible suppliers in the world. So I remember there were others, but I don't recall their names.

Q. That's what I'm asking as to whether you recall any other names.

A. I recall Ipca, but I don't recall exactly the details about Ipca.

Q. Do you recall discussions when you were there at Vyera about whether the company should contract with an API supplier to be the backup supplier for Fukuzyu?

A. Very briefly.

Q. Did you consider it necessary to secure a backup supplier after you signed the supply agreement with Fukuzyu?

A. Not at that time, no.

Q. The contract was signed in 2017?

A. Correct.

Q. And you left the company sometime in mid 2017?

A. Correct.

Q. Was there any time from the time the company signed the contract with Fukuzyu in 2017, and you left that you considered

getting a backup supplier?
A. No. That's what I meant. During those six months I was with the company, after signing the agreement, I did not think it was important at that time for that.
Q. Thank you.
MR. MEIER: Ms. Guy, would you please put Government Exhibit 1479 on the screen.
Q. If you could just take a moment, like you're doing, to familiarize yourself with the cover. Again, I am going ask you to whether you have seen this before and whether you know what it is?
A. Yes, I have seen it before and I know what it is.
Q. What is it?
A. It was a call for an extraordinary general meeting of shareholders to be held in June 2017.
Q. As I think you just explained, extraordinary general meeting is a shareholder meeting as opposed to a board meeting, correct?
A. Correct.
Q. At this time, 21 June 2017, you were Vyera's interim chief executive officer, correct?
A. Yes.
Q. And you were nominated by the then Phoenixus board to become a board member, correct?
A. Yes.

Q. By the time of this board meeting Mr. Shkreli was no longer with Vyera or Phoenixus, correct?
A. Yeah. There was no Phoenixus at this time. Yes. Turing or what it became after.
Q. I think we talked about that at the very beginning. I was just going to use the term Vyera and Phoenixus, but I understand what you mean. By the time of the extraordinary general meeting, Mr. Shkreli had been arrested for securities fraud and he had resigned as the CEO and he had resigned from the board, correct?
A. Correct.
Q. Is it correct that the parent company for Vyera, which was then called Turing, is a Swiss corporation?
A. Yes.
Q. That's why it says Baar Switzerland. That was the Swiss headquarters for Turing Pharmaceuticals AG?
A. Yes.
Q. AG means essentially a corporation in German?
A. I believe so.
Q. Under Swiss corporate law, any shareholder with enough shares in Phoenixus can call an extraordinary general meeting, correct?
A. I think so, but I don't remember the bylaws.
Q. You recall that Mr. Shkreli actually is the person who called for this particular extraordinary general meeting,

correct?

A. I believe so.

Q. Do you recall that Mr. Shkreli had enough shares in the parent company at the time to call this meeting by himself?

A. As I said, I don't remember in detail the bylaws, but I remember that he had the right to call for those meetings.

Q. And he called for this particular meeting.

A. I believe so. There were several meetings during my tenure that would call and would cancel. I am not sure which one in particular by whom.

MR. MEIER: Let's turn to page 2, Roman numeral II. It's down at the bottom of the page. Thank you, Ms. Guy.

THE COURT: Is this exhibit in evidence?

MR. MEIER: I apologize, your Honor. My apologies. I meant to request that this be moved in evidence. Thank you for the reminder.

THE COURT: Received.

(Government Exhibit 1479 received in evidence)

Q. Looking at agenda item number II it says: Agenda items requested by the Turing Pharmaceuticals, AG board of directors, election of Eliseo O. Salinas, etc.

One of the agenda items at this extraordinary general meeting was to nominate a slate of members to the board of directors, correct?

A. Correct.

Q. At this meeting do you recall that there were actually two competing slates of nominees for the board?
A. I do.
Q. The current board at the time had proposed a slate of directors, including you, and Mr. Shkreli had proposed a very different slate of directors, is that correct?
A. Correct.
MR. MEIER: If we could scroll down a little bit, Ms. Guy. I'm sorry. Turn to page 3 and then where it says proposals, an explanation of the board of directors. Up near the top there is, in italics, proposals and explanations of the board of directors.
Q. It says the board of directors proposes that the shareholders fully elect you and the other members that the board had put forward, correct?
A. Correct.
Q. It also explains in that same paragraph that the board of directors overwhelmingly supports these candidates, as do many of the companies' large investors, due to the vast business experience each has had in the pharmaceutical industry. Do you see that?
A. I do.
Q. That's a reference to you, Mr. Lavotha and Mr. Berman.
A. Yes.
Q. Then it actually explains the qualifications, your

qualifications, Mr. Lavotha's and Mr. Berman, correct?
A. Correct.
Q. I am not going to go and read all of those. We will just leave it at that.
MR. MEIER: Let's turn to page 5 of Government Exhibit 1479. If we could highlight the top agenda, item number I.
Q. That says: Agenda items requested by Martin Shkreli, election of Akeel Mithani, Kevin Mulleady to the board of directors. Do you see that?
A. Yes.
Q. We talked about Mr. Mithani and Mr. Mulleady earlier this afternoon, correct?
A. Not with me.
Q. That's right. You are right. That was with Mr. Pelliccione. Thank you.
Mr. Shkreli, was he proposing a slate of directors to replace the current board?
A. Yes.
Q. One of the reasons he gave is, he had informed the board that he was not satisfied with the current board, nor with how the company was being run, correct?
A. Correct.
Q. And you also thought that Mr. Shkreli wasn't happy with you and what you were doing as the interim CEO, correct?
A. Yes.

Q. And, in fact, Mr. Shkreli had been very quote hostile and negative towards you, correct?
A. Yes.
Q. And he had sent you threatening e-mails, correct? I'm sorry. Threatening mail.
A. I remember only one e-mail that was threatening.
Q. Mr. Shkreli's threatening mail said you were "a cockroach that needed to be stomped or crushed." Do you remember that?
A. I do remember that, yes.
Q. And you thought Mr. Shkreli was hostile to you because you did not want him to remain associated with Vyera after he had stepped down, correct?
A. That was my belief.
Q. Right. That's all I'm asking. You thought Mr. Shkreli was hostile to you because you did not want him to remain associated with Vyera after he stepped down?
A. Yes.
Q. And you didn't want Mr. Shkreli to have an active role in the company after he stepped down?
A. Yes.
Q. And it was your impression that Mr. Shkreli wanted to continue to have an active role in the company, even after he stepped down?
A. Yes.
Q. In fact, Mr. Shkreli wanted to participate in a meeting of

the executive committee after stepping down.

A. Yes.

Q. And you thought that Mr. Shkreli's proposed slate of directors lacked experience and competence, correct?

A. Correct.

Q. And the existing board recommended against Mr. Shkreli's proposed slate of board of directors.

A. Yes.

MR. MEIER: If we could turn to page 6 of Government Exhibit 1479. We are still looking at the extraordinary general meeting notes. If you actually do the very top part, include the very top. Thank you.

Q. This is where the board of directors proposes that the proposal of Martin Shkreli be fully rejected, right?

A. Right.

Q. Then the board gives a number of reasons, correct?

A. Correct.

Q. Again, I am going to stay away from reading all of it. But one bullet point is a lack of transparency, correct?

A. Yes.

Q. Do you remember what that was generally about?

A. In general terms, that Martin Shkreli was not forthcoming with his reasons for doing what he was doing, and his business relationships with the candidates he was appointing, trying to appoint.

MR. MEIER: If we could go to the second bullet point, Ms. Guy.

Q. The second reason the board gave for rejecting Mr. Shkreli's slate was because of what it perceived as undue involvement of Martin Shkreli in the company, correct?

A. Correct.

Q. We talked a little bit about that a moment ago, at least your perceptions of that a moment ago.

A. Yes.

Q. Let's look at the second bullet, undue involvement of Martin Shkreli, and go to the fourth line down. I think it's the fourth one. There it is. Thank you.

One of the concerns the board had was that Mr. Shkreli publicly holds himself out as speaking for the company when in fact he has no operational or business responsibilities. You see that?

A. I do.

MR. MEIER: Let's go three lines down. Thank you.

Q. There the board explains that as a result of their distinct lack of qualifications, and that's a reference to Mr. Shkreli's slate, correct?

A. Yes.

MR. RUDOWITZ: Objection, your Honor. This is all hearsay within hearsay.

THE COURT: Overruled.

Q. It says: As a result of their distinct lack of qualifications and the fact that they were nominated by Mr. Shkreli and have apparent conflicts of interest further described below, the board believes that in the case of their election, many third parties, including regulatory authorities, will likely deem the newly elected board members to be serving merely as straw men acting on Mr. Shkreli's behalf, and could further deem Mr. Shkreli to be in a position of influence, direct, or control the board and thus the company as well. You see that?

A. I do.

Q. When it says the company, it's talking about what we have been calling Vyera all day today, right?

A. Right.

Q. The operating company, the company that owns Daraprim, correct?

A. Yes.

Q. And the company that you were doing the research and development for, correct?

A. Yes.

Q. And the company that Mr. Pelliccione works for.

A. Yes.

Q. As it indicates there, one of the concerns the board had was the lack of qualifications and conflicts of interest.

MR. MEIER: If we could go down to the third bullet

point right below where we have been highlighting, Unhighlight and move down. We will talk a little bit about that.

Q. If I understand this correctly, a third reason the board gave for opposing the slate Mr. Shkreli had put forward is that the people he had put forward lacked qualifications and they have conflicts of interest, correct?

A. Correct.

Q. And, apparently, Mr. Shkreli had provided CVs on some of these different individuals, correct?

A. Yes.

MR. MEIER: Let's go to the next page, please. If I could just focus on Akeel Mithani on the top first.

Q. This board meeting is held in 2017, correct?

A. Yes.

Q. According to the board minutes here or the minutes from the extraordinary general meeting, Mr. Mithani had just graduated three years earlier from college, correct?

A. Correct.

Q. Do you recall whether he had any background in the pharmaceutical industry?

A. My recollection is that he didn't.

Q. Do you recall whether he had any experience of holding any kind of a position of responsibility in any kind of company?

A. He got some association with the company held by Martin Shkreli, but that's all I knew.

Q. Do you see the last part of the entry there where it says the board believes? Do you see that?

A. I do.

Q. The board believes that Mr. Mithani's current association with Mr. Shkreli constitute a direct conflict of interest with the company and leaves Mr. Mithani unable to act as an independent board member.

Do you have any recollection sitting here today what that conflict of interest was?

MR. RUDOWITZ: Objection, your Honor. That statement lacks foundation, personal knowledge.

THE COURT: Overruled.

A. I believe that Akeel Mithani had some participation in some company that Martin Shkreli had created, a small endeavor, but I don't recall the details.

MR. MEIER: I am going to go ahead and move next to the one for Mr. Mulleady. It's sort of in the middle of the page, Kevin Mulleady.

Q. Do you see where it says Kevin Mulleady is a former Turing employee and has been associated with Mr. Shkreli for many years. You see that?

A. I do.

Q. Do you remember what Mr. Mulleady did when he was a Turing employee?

A. I remember not knowing what he was doing. He was present

in the office, but nobody knew exactly what his role was.

Q. Do you recall whether he was part of what was known as the business development group at the time?

A. Not exactly, no. He was not part of that group, for as much as I knew.

Q. And do you recall that the board had concerns also that Mr. Mulleady had conflicts of interest with Mr. Shkreli?

A. Yes.

Q. That was because of other business ventures that they were involved in? Is that correct?

A. Correct.

Q. Do you see where at the end of that block where it says the board believes that Mr. Mulleady is not suitable to serve as an independent member of the board. Do you see that?

A. I do.

Q. Did you agree with that?

A. Yes.

MR. MEIER: Let's turn to page 8, please. There is an underlined portion right there. Yes. Perfect.

Q. The board wrote this underlined portion: The board is of the opinion that, in light of all of the above-mentioned negative implications for the company, the election of the slate of candidates put forward by Martin Shkreli would be disproportionately risky and outright unreasonable. You see that?

A. I did, yes. I'm seeing that.
Q. All of this board meeting and this discussion was occurring after Mr. Shkreli had already left the company, correct?
A. Yes.
MR. MEIER: You can take down Government Exhibit 1479.
Q. Let me summarize then. The examining board put forward a slate of what you believe to be competent and experienced people, correct?
A. Yes.
Q. Mr. Shkreli put forward a slate of directors that lacked experience?
A. Yes.
Q. And the board strongly recommended against Mr. Shkreli's state of inexperienced directors?
A. Yes.
Q. But what actually ended up happening?
A. The opposite.
Q. Which is?
A. The majority of the shareholders elected the slate proposed by Martin Shkreli.
Q. That's because Mr. Shkreli owned the largest portion of the company?
A. I don't know that for a fact. He owned, he was the largest investor, but he needed other investors to vote with them.
(Continued on next page)

Q. So Mr. Shkreli was successful getting his slate of directors elected even though the existing board viewed them as unqualified?

A. Yes.

Q. In doing so, Mr. Shkreli demonstrated that if he wasn't happy with the current board of directors, he could change the makeup of the board, correct?

A. Yes.

Q. And shortly after the meeting in June of 2017, you left the company?

A. Yes.

Q. And you were replaced by Mr. Mulleady as the chief executive officer?

A. Yes.

Q. So, in the end, you were out and Mr. Shkreli's people were in?

A. Yes.

MR. MEIER: Thank you, Dr. Salinas.

No further questions, your Honor.

CROSS-EXAMINATION

BY MR. RUDOWITZ:

Q. Good afternoon, Dr. Salinas.

A. Good afternoon.

Q. My name is AJ Rudowitz. I'm an attorney representing Mr. Shkreli in this action.

I believe that you testified earlier that you've worked in the pharmaceutical industry for approximately 30 years; is that right?

A. A little bit over 30 years.

Q. And you've worked for a number of medium and large size pharmaceutical companies, including Wyeth, Shire, and Elan?

A. Yes.

Q. I believe you also testified that your primary experience has been in the areas of research and development, right?

A. Yes.

Q. Dr. Salinas, you joined Vyera — I understand it was formerly called Turing, but we'll refer to it as Vyera today — back in June of 2015; is that right?

A. Yes.

Q. And you were hired as president and head of research and development, correct?

A. Correct.

Q. I believe you testified earlier that Mr. Shkreli hired and interviewed you for that position?

A. Yes.

Q. What was it that made you decide to join Vyera?

A. The fact that they had the ambition to become an important research company in central nervous system, or CNS, and/or the research and development CNS company, and that they were well funded, they have the means to accomplish that objective, and

they have complicated research programs that required, in my opinion, someone with a lot of experience, and that attracted me.

Q. I believe you also discussed earlier that you had conversations with Mr. Shkreli concerning Vyera's business model; is that right?

A. That's right.

Q. What did you understand the role to be of research and development in Vyera's business model?

A. The engine that R&D would be the most important thing that we would be doing, that the acquisition of some products at the end of their marketing life would be a supplement of the funding necessary to develop those research programs.

Q. As the engine of Vyera, when you were working at Vyera in 2015, what types of research and development projects and programs were you working on?

A. There were seven or eight. Do you want me to give you a brief summary of each of them?

Q. A brief summary would be great.

A. There were three, what is called, late stage programs, programs that were likely to become marketed products in a short period of time, two or three years.

One was a ketamine program, an intranasal form of ketamine for the treatment of depression and suicide.

Another was oxytocin, which was originally a drug

intended for lactation, to stimulate lactation in mothers, but we thought about developing oxytocin for CNS conditions like autism and disorders of that nature.

Another one was an antiepileptic drug which exist in Europe, but did not at that time in the U.S., called Stiripentol.

Those were the three most advanced, and behind those, there were a number of programs for rare CNS disorders in collaboration with different several academic institutions.

And then when Turing acquired Daraprim, as a condition of that acquisition, I requested that we did research in toxoplasmosis, and we started doing research in toxoplasmosis, also.

Q. Mr. Shkreli left his position as CEO just about six months after you joined the company, in December 2015, right?

A. Yes.

Q. I know you just mentioned Daraprim. So Vyera acquired Daraprim in August of 2015?

A. Yeah, it was the summer, I believe August.

Q. I believe you testified earlier that you disagreed with the price increase of Daraprim once Vyera acquired it; is that right?

A. Yes.

Q. In your experience in the industry, it's true that drugs that affect a rare condition are extremely expensive and can be

priced at 300,000, 400,000, or 500,000 dollars per patient per year; is that right?

A. Yes.

Q. Dr. Salinas, are you familiar with the potential side effects of Daraprim?

A. Yes.

Q. If a toxoplasmosis patient takes too much Daraprim, what are the side effects?

A. Daraprim inhibits the action of an enzyme that is necessary for the cells of the patient to regenerate, so it affect our bone marrow, which produces the blood cells, which is one of the most active tissues regenerating constantly. So Daraprim could have a very negative effect on the production of blood cells, and that's one example.

It has very toxic effects in the embryo during the first trimester of the pregnancy, which is the time which you would like a drug against toxoplasmosis effective because it's the time when the baby is most susceptible if the mother contracts the parasite at the time.

And there are other side effects.

Q. Conversely, if a toxoplasmosis patient takes too little Daraprim, what are the side effects?

A. I wouldn't call them side effects, but the parasite infection will not be treated, and the patient could die of the parasitic infection.

Q. Is it correct that taking the correct dosage of Daraprim is important for treatment and for safety?

A. Yes, it's critical.

Q. And specialty pharmacies can help ensure that patients take the correct dosage of Daraprim, right?

MR. MEIER: Your Honor, I am going to object. There's been no foundation laid for Dr. Salinas knowing anything about what specialty pharmacies do.

THE COURT: I thought your objection was beyond the scope.

Wait a minute. Have you both subpoenaed this witness?

MR. MEIER: Yes.

MR. RUDOWITZ: Yes, your Honor.

THE COURT: Okay. So get beyond the scope. You may lay a foundation.

BY MR. RUDOWITZ:

Q. Mr. Salinas, are you familiar with specialty pharmacies?

A. Peripherally familiar, yes.

Q. What's the difference between -- what benefits, if any, does a specialty pharmacy offer that a retail pharmacy does not?

A. Typically, it affect drugs that are difficult to take, require more explanation to the patient, or simply very expensive.

Q. Dr. Salinas what, if anything, can be done to help ensure

patients take the correct amount of Daraprim?
A. Well, first, education, of course, medical education, the appropriate promotion from the sponsor explaining how the drug should be taken, and to a certain extent, the specialty distribution adds another layer of information and protection.
Q. What other pharmaceutical must be taken with Daraprim to treat toxoplasmosis, if any?
A. Leucovorin.
Q. Are there instances where a toxoplasmosis patient cannot take Daraprim for treatment?
A. Yes. If the patient had a previous intolerance to pyrimethamine, that will be an example.
Q. I believe you discussed earlier issues with embryos. Is Daraprim the preferred treatment for toxoplasmosis patients who are pregnant?
A. Not in the first trimester. It's contraindicated in the first trimester. Later on, it could be used, but not in the first trimester.
Q. And Daraprim -- based on your experience, can Daraprim be administered to treat toxoplasmosis patients with a sulfa allergy?
A. Pyrimethamine can be given to patients that has a sulfa allergy. Not Bactrim, but pyrimethamine can be given to patients that had a sulfa allergy.
Q. With Daraprim -- is Daraprim often treated in combination

with a sulfa?
A. Yes.
Q. Based on your experience, in general, what pharmaceutical is most commonly used for the treatment of toxoplasmosis?
A. In the U.S., it would be Daraprim -- sorry, excuse me, I take that back. The most commonly used is Bactrim, which is trimethoprim and sulfamethoxazole. That's the most commonly used, although it is not approved for that indication.

The most knowledgeable experts on toxoplasmosis regret that fact because they think that pyrimethamine is better, but I believe, in volume, the most commonly used is Bactrim.

Q. You testified earlier about a company called Fukuzyu, correct?
A. Correct.
Q. And you were involved in identifying Fukuzyu as a potential supplier for pyrimethamine API, correct?
A. Yes.
Q. It's correct that you did not identify Fukuzyu as a potential supplier until 2016?
A. Yes.
Q. In 2016, you became concerned that Vyera might run out of pyrimethamine API supply and, thus, would not be able to continue manufacturing Daraprim; is that correct?
A. Yes.
Q. Up until that point, when you began searching for an API

supplier, Vyera had been using the existing pyrimethamine API inventory that was acquired from the previous owner of Daraprim, right?

A. Right.

Q. So you began your search for an API supplier because you were concerned with supply of pyrimethamine API, correct?

A. Yes, very concerned.

Q. And you didn't have any discussions with Mr. Shkreli about the Fukuzyu API supply agreement; is that right?

A. Right. He wasn't there anymore.

Q. And Vyera entered into the supply agreement with Fukuzyu in approximately January of 2017; is that right?

A. Right.

Q. So Vyera went approximately one and a half years after acquiring Daraprim before entering into a supply agreement; is that right?

A. That's right.

Q. And you were involved in the negotiations of the supply agreement between Vyera and Fukuzyu?

A. Yes, I was.

Q. You had primary oversight of the negotiations?

A. Yes.

Q. I believe that you testified earlier that in the negotiations, getting an exclusive supply provision was a goal for Vyera, correct?

A. Was a goal, yes.
Q. It was a goal, but it was not the most important goal, right?
A. Correct.
Q. What was the most important goal?
A. Getting the supplier.
Q. Now, Vyera and Fukuzyu did agree to an exclusivity provision, right?
A. Right.
Q. Why did Vyera include an exclusivity provision in the supply agreement with Fukuzyu?
A. Because we were unable to anticipate the volume we would need. Our plans were very aggressive, and we had reasons to believe that we could be successful in increasing the use of Daraprim in the approved indication, and we had research programs in extending that if we were successful in both areas that were needed, it could be ten or fifteen times higher than what would have been without those programs.
Q. So you were concerned for API supply both for Daraprim, as well as the anticipated or hopeful products that were in development in the R&D pipeline; is that correct?
A. Yes. In particular, we're thinking about an intraocular form of pyrimethamine. We didn't talk about that. That's why I mentioned it.
Q. Dr. Salinas, did you try to negotiate any other terms that

would help ensure supply of pyrimethamine API, such as a minimum volume requirement?

A. That was part of the discussion. I remember, also, the quality agreement that was very important for us.

Q. And you had discussions with Fukuzyu about prioritizing sales of pyrimethamine API to Vyera over sales to its other customers outside of the United States, right?

A. That was our concern, that we would be able to get all the pyrimethamine we would need, yes.

Q. So you contemplated numerous types of provisions in the supply agreement that would help ensure API supply, including the exclusivity provision; is that correct?

A. That's correct.

Q. And in your experience in the industry, are exclusive supply agreements common?

A. Very common.

Q. With all of the companies that you worked for previous to Vyera, did they all have exclusive supply agreements?

A. I've been with many companies. I cannot guarantee all of them had, but the important products for each of the companies I worked for had -- or we intended to have exclusive supply agreements.

Q. I believe plaintiffs' counsel asked you earlier about a concern of generic entry.

Do you remember that --

A. I do.
Q. -- in general.
But, in fact, at the time you were negotiating the supply agreement with Fukuzyu, generic competition was not a concern of yours; is that right?
A. That's right.
Q. After Vyera signed --
THE COURT: So, counsel, I do not understand the distinction you're making. If this is important to you, you need to explain the difference.
MR. RUDOWITZ: Okay, your Honor.
BY MR. RUDOWITZ:
Q. Earlier today, plaintiffs' counsel was asking you, in general, about whether you were concerned of generic competition, and I believe that you did not testify that generic competition was a concern of yours; is that right?
A. That is right.
Q. Now, generic entry was discussed earlier as well, and I believe that you have testified, generally, that generic entry would have been a concern specifically with respect to Fukuzyu because it would impact supply?
THE COURT: So, I'm sorry, I misled you, counsel. I didn't really want you to explain it; I wanted the witness to explain it. To the extent you can engage in nonleading questions of the witness, that would be helpful. I'm sorry if

I misled you.

MR. RUDOWITZ: Understood, your Honor. I apologize.

BY MR. RUDOWITZ:

Q. Dr. Salinas, can you explain why -- strike that. I'm sorry.

Can you explain why generic competition was not a concern of yours, but generic entry may have been?

A. Because of the business model. Generic companies are based on large volumes and low prices. Large volumes, Advil, ibuprofen, those kind of drugs — that's the business of generic companies. Large volumes, small prices, small cost. That's why generic companies do not invest in research and development. That's not their objective. It's to make cheap large volumes of medication.

And pyrimethamine and Daraprim was the opposite, a very small volume, very small number of patients, and that's why, for me personally, but that was my personal opinion, while the entry of generic could be a theoretical concern, I thought that that was unlikely to happen because if it were to happen, one, two, three, five, ten generic companies would enter the market, the market would collapse, and it would be the end of the market for those generic companies because there wasn't enough volume for them.

So I thought -- and some of my colleagues disagreed, but I was of the opinion that that was not a major concern.

Q. Conversely, why were you concerned with generic companies acquiring API from Fukuzyu?

A. I was concerned about us, Turing, or Vyera having enough API to do all our ambitious projects. To give you an idea, if we were successful -- let me step back.

Encephalitis toxoplasmosis is recognized by every physician. There's no undertreatment of toxoplasmosis encephalitis. There's a huge undertreatment of retinal toxoplasmosis, which is the most common form. Ophthalmologists, in the U.S. in particular, but also outside of the U.S., have this misconception that the infection should only be treated if it affects the center of the eye, the macula, and if the parasite is detected outside of the macula, in the periphery, they don't treat it, and that's not good medicine, but that's the way it is done.

If ophthalmologists, the general ophthalmologists, were to treat all the cases of toxoplasmosis that exist in this country, the volume of Daraprim needed could be about ten times higher, because those are the numbers. So even if our research projects were not successful, just merely by putting ocular toxoplasmosis in the radar screen of the primary care ophthalmologists would have generated an increase in our need of pyrimethamine, and, therefore, I was afraid of any competition, not generic. I was afraid of any other competitor that could require additional pyrimethamine.

Fukuzyu was the only available supplier at the time, but they were selling a number of generics — I don't know, ten, twenty — and they have a small percentage of their capacity allocated to pyrimethamine. If our needs increase by ten times, I was concerned that they would not be able to support our needs.

Q. And to try to summarize, because I think I may have done an earlier poor job of asking the question, to summarize, generic competition was not a concern of yours because the generic business model did not fit Daraprim, and, thus, you did not see it as a threat, but generics obtaining API from Fukuzyu was a concern because of your high aspirations requiring high volume?

MR. MEIER: Your Honor, I object; this is argumentative.

THE COURT: Sustained.

BY MR. RUDOWITZ:

Q. Dr. Salinas, after signing the supply agreement with Fukuzyu, you considered the need for a backup or additional API supplier for pyrimethamine API?

A. I was asked the question at that time, if we should or should not look for a backup supplier.

Q. Based on your experience, it's normal business practice in pharmaceuticals to have a backup supplier for important products, correct?

A. Yes.

Q. And in your work at previous companies, the important products at those companies had backup suppliers, correct?
A. Typically, yes.
Q. Dr. Salinas, I believe you have discussed a company called RL Fine earlier.

Do you remember that?

A. I do.

MR. RUDOWITZ: Justin, can you bring up GX 1058.

Q. Dr. Salinas, have you seen this email before?
A. I hate to say that, but it's, again, a black screen.

THE COURT: What is the document number again? I'm sorry.

MR. RUDOWITZ: GX 1058, your Honor.

THE COURT: Thank you.

THE WITNESS: It's still a black screen. I'm sorry.

Now it's back. Okay, I'm seeing an email here.

BY MR. RUDOWITZ:

Q. Dr. Salinas, have you seen this email before?
A. Yes, I remember this email.
Q. And this is an email chain with the original email sent by Patrick Crutcher to you, copying Nick Pelliccione and Gopal Krishna --
A. Yes.
Q. -- on November 17, 2016; is that right?
A. Yes.

MR. RUDOWITZ: Your Honor, we move to admit GX 1058.

THE COURT: Received.

(Government's Exhibit 1058 received in evidence)

BY MR. RUDOWITZ:

Q. Dr. Salinas, what is the subject line of the email?

A. RL Fine Chemicals.

Q. Do you see in Mr. Crutcher's email to you, first paragraph, third sentence, he writes, "It may make sense for us to get in touch with them to discuss this as a backup supplier."

Do you see that?

A. I do.

Q. In the first bullet point, Mr. Crutcher writes, "RL Fine Chemicals was contacted to determine if they have taken any steps to file a U.S. DMF and make the API available to USA generic companies."

Do you see that?

A. I do.

Q. And then on the following sub-bullet point, under that, Mr. Crutcher writes, "RL has validated the process, and the product is ready, as is a DMF, for submission to the FDA."

Do you see that?

A. I do.

Q. Do you know what product Mr. Crutcher is referring to in that sub-bullet?

A. Yes. He's referring to pyrimethamine.

Q. Was this the first time that you had heard of RL Fine being a potential backup supplier for pyrimethamine API for Vyera?
A. I believe so, but I don't know. But this was before we had the agreement signed with Fukuzyu.
Q. And above that, you email in response, and you write, "Good idea. Gopal, Nick: Let's discuss."
Do you see that?
A. I do.
Can I make a clarification?
Q. Yes.
A. So when I said I did not think it was necessary to have a backup supplier at that time, I meant after signing the agreement with Fukuzyu. Before signing the agreement with Fukuzyu, the backup is that for me, if Fukuzyu doesn't work, if Fukuzyu doesn't want to do business with us, what do we do, we need a backup that give us. So the word backup has two meanings in this context.
Q. Okay. So Vyera was aware of RL Fine's ability to manufacture pyrimethamine API in 2016, right?
A. Right.
Q. Based on your experience, some generic pharmaceutical companies do not need to rely on a DMF from outside API manufacturers because they have their own manufacturing processes; is that right?
A. That's right.

Q. And those generic companies would just create their own DMF internally and file that with the FDA; is that right?
A. That is right.
Q. So a generic company, like Perrigo or Mallinckordt, could start and generate their own DMF?
A. Yes, a large company could start the process without the need of an outside DMF. Any large generic company could have manufactured pyrimethamine at any time.
Q. Based on your experience, that process could be done in a matter of a few months?
MR. MEIER: Your Honor, I am going to object again. There's no foundation for --
THE COURT: Sustained.
BY MR. RUDOWITZ:
Q. Dr. Salinas, are you aware of any generic pharmaceutical companies creating their own DMFs internally?
A. Yes.
Q. How quickly can a DMF be created internally?
MR. MEIER: Objection, your Honor.
THE COURT: Sustained.
Q. In your experience, and based on your knowledge, what's the quickest that you know a generic pharmaceutical company to create a DMF internally?
MR. MEIER: Objection, your Honor.
THE COURT: Sustained.

I'll let you lay a foundation, counsel, but you have to lay a foundation.

MR. RUDOWITZ: Understood, your Honor.

BY MR. RUDOWITZ:

Q. Dr. Salinas, do you know --

THE COURT: Have you ever worked at a company -- have you ever worked at a large generic manufacturing company?

THE WITNESS: No.

THE COURT: Have you ever worked at a large pharmaceutical manufacturing company that's created its own API for the first time?

THE WITNESS: I believe, yes. Wyeth, at the beginning of my career.

BY MR. RUDOWITZ:

Q. Dr. Salinas, how long did it take --

THE COURT: Well, no, I got you started, counsel. You're going to have to lay a foundation.

MR. RUDOWITZ: Okay.

BY MR. RUDOWITZ:

Q. Dr. Salinas, what company was that at?

A. Wyeth.

Q. And, Dr. Salinas, what drug was that?

A. I don't recall. There were many drugs manufactured by Wyeth, and in discussions with the CMC, that topic would come up and -- but I cannot pinpoint to a specific drug.

Q. Do you recall how long it would take -- how long it took?

THE COURT: That's not a foundation, counsel. Let's move on.

MR. RUDOWITZ: All right.

BY MR. RUDOWITZ:

Q. Based on your experience, whether to have a backup supplier is a business decision, right?

A. It is.

Q. Moving forward, you eventually became interim CEO of Vyera in April 2017?

A. Yes.

Q. When you were CEO of Vyera, you were the one making the day-to-day decisions for the company?

A. Yes.

Q. While you were CEO, did you often speak with Mr. Shkreli?

A. Not often. Once, I believe. Or twice.

Q. After Mr. Shkreli stepped down as CEO, he did not participate in any executive committee meetings?

A. He did not participate.

Q. And you would agree with me that after Mr. Shkreli stepped down as CEO, that he did not retain significant influence on the company?

A. Yes, I agree.

MR. RUDOWITZ: Justin, can you pull up GX 1479 on page 6.

Q. Dr. Salinas, I believe you had looked at this document earlier today.

Do you remember that?

A. Yes.

Q. The second bullet point, fourth line down, I think you had also looked at that, that starts with the word "there."

A. Yes.

Q. "There are times when Mr. Shkreli publicly holds himself out as speaking for the company when, in fact, he has no operational or business responsibilities."

Do you agree that Mr. Shkreli had no operational or business responsibilities for Vyera at that time?

A. I do.

Q. And it was after --

MR. RUDOWITZ: You can get rid of that, Justin.

Q. It was after Mr. Shkreli stepped down as CEO that Vyera began negotiating with Fukuzyu, right?

A. Right.

Q. And it was after Mr. Shkreli stepped down as CEO that Vyera entered into the agreement with Fukuzyu, correct?

A. Correct.

Q. And it was after Mr. Shkreli stepped down as CEO that Vyera identified RL Fine as a potential backup supplier, correct?

A. Correct.

MR. RUDOWITZ: No further questions, your Honor.

MR. MEIER: Yes, your Honor. Thank you.

REDIRECT EXAMINATION

BY MR. MEIER:

Q. I have some follow-up questions, Dr. Salinas.

Do you recall the discussion with Mr. Rudowitz where Mr. Rudowitz was drawing a distinction between concerns about generic competition and generic entry?

A. I do.

MR. MEIER: Could we pull up Government Exhibit 1056, which has already been admitted in evidence and we looked at earlier today. And if we could go to page 2, item number 6, which we also talked about earlier today.

Q. The contemporaneous records of your time at the company show that you were concerned about generic competition, correct?

A. As a challenge to the volume we needed, yes.

Q. If you look at number 3, it says, "Generic pyrimethamine will hamper these activities and may leave toxoplasmosis a forgotten disease with insufficient therapeutic effects."

So, again, you were concerned about generic competition, weren't you?

A. My main concern was the volume. My main -- if Fukuzyu had given a supply agreement without an exclusivity clause, that would have been good enough. I would have had half the loaf of bread I needed. The exclusivity gave more comfort. That's the

distinction.

Q. My question was: You were concerned about generic competition at the time, correct?

A. To a certain extent, yes.

Q. If you look at number 8, it says, "Generic companies sell the drug at significantly lower prices, which is not a benefit to Fukuzyu either on the sales."

Do you see that?

A. I do.

Q. So the contemporaneous records show that when you were working at Vyera, you were concerned about generic competition, correct?

A. I was concerned about the generics or branded products taking away the volume we would need. So, yes, that includes generics.

Q. Okay. Thank you.

MR. MEIER: We can take that down.

Q. You had talked about backup suppliers with Mr. Rudowitz.

Now, during the time you were at Vyera, Vyera never got a backup supplier for Vecamyl, correct?

A. I believe it was the case yes.

Q. And you never got a backup supplier for Daraprim while you were at Vyera?

A. Correct.

Q. When Mr. Rudowitz showed you Government Exhibit 1058, that

talked about RL Fine, you drew a distinction between two different types of backup suppliers, correct?

A. Correct.

Q. One type of backup supplier was if you didn't get the contract with Fukuzyu, your plan B would go to RL Fine, correct?

A. Correct.

Q. But you were not talking about RL Fine at that time as a second supplier to Fukuzyu, were you?

A. Correct.

Q. Now, Mr. Rudowitz also asked you about specialty distribution, correct?

A. Yes.

Q. And during the time you worked at Vyera, Vyera had Daraprim specialty distribution, correct?

A. Yes.

Q. But, as we also talked earlier today, Daraprim is a 68-year-old product, correct?

A. Yes.

Q. Do you know for how many years Daraprim was in specialty distribution?

A. Very little time before Vyera acquired it.

Q. It was only shortly before Vyera acquired it that it was put into specialty distribution in the first place, correct?

A. Correct.

Q. So for most of the history of the product, it was not in specialty distribution, correct?
A. Correct.
Q. You testified earlier, when Mr. Rudowitz was talking to you, about how you were attracted to come to Vyera because you thought it might become an important research company, correct?
A. Correct.
Q. And you were hopeful that research and development would be the most important thing the company does, correct?
A. Correct.
Q. In the time that you were at Vyera, you actually never successfully developed and launched a product, did you?
A. Not a commercial product, but we filed for INDs.
Q. Yes, investigative new drug applications.
A. Correct.
Q. That's something you do pretty early in the process with the FDA, right?
A. It depends what you call "early."
Q. Well, with the FDA, it's one of the first --
A. Oh, we did, yes. The FDA does not regulate research done in animals.
Q. You might do research before you file an IND, but an IND is still early in the FDA regulatory process?
A. Correct.
Q. And it means that there could still be years and years

before you actually have a product ready to commercialize, correct?

A. Yes.

Q. And in the time you were at Vyera, you didn't actually commercialize any products?

A. Correct.

Q. To the best of your knowledge, do you know whether Vyera has ever gotten FDA approval to market a new product?

A. To the best of my knowledge, no, they haven't.

Q. Now, during the six months or so that you were interim CEO, you indicated that Mr. Shkreli didn't have significant influence on the company, correct?

A. In the operation of the company, yes.

Q. But that was, of course, until he managed to replace the board and to replace you, correct?

A. Correct.

MR. MEIER: No further questions, your Honor.

THE COURT: Any further questions, counsel?

MR. RUDOWITZ: No further questions, your Honor.

THE COURT: Thank you.

So, you joined the company, you're very unhappy with the price of Daraprim, you become interim CEO.

Did you take steps to reduce the price of Daraprim?

THE WITNESS: We had discussions --

THE COURT: Did you or didn't you?

THE WITNESS: Oh, no. Well, sorry, yes. When I came --

THE COURT: What steps did you take to reduce the price?

THE WITNESS: Went on a case-by-case with certain providers. Certain hospitals were given some discounts and -- but not an across-the-board discount.

THE COURT: So the ocular toxoplasmosis that you hoped to develop another product to treat, that would be more widely distributed and used by medical practitioners, did I understand that correctly, that was your hope?

THE WITNESS: No. There were two aspects. One is to educate about the use of the existing product. The existing Daraprim could be used to treat the peripheral toxoplasmosis, that's number one.

The second was to generate a new product that will be an intraocular formulation that will be injected inside the eye. That's the research program. But we had two research activities, and with FDA, we had agreed that if we were -- the problem, because it was such an old drug, there was not enough research performed in 1953, but since then, many people have conducted research with Daraprim in ocular toxoplasmosis. We were collecting data from France and Brazil to show that the use of Daraprim in its existing form for ocular toxoplasmosis was a good thing for patients, and, in addition, we had this

intraocular plan. So there were two ways to tackle that problem.

THE COURT: Okay.

So you hoped to educate the medical profession to more widely use Daraprim, you hoped to develop a new product for injection into the eye.

Would that use the same API?

THE WITNESS: Yes.

THE COURT: Pyrimethamine?

THE WITNESS: Yes.

THE COURT: So when you went to Fukuzyu to obtain a supply of pyrimethamine, you were running out of the supply that came to you when Daraprim was purchased, you needed the API?

THE WITNESS: Yes. Not immediately, but the manufacturing person reporting to me came to alert me, saying if we continue on the trend, and if things go well, we're going to run out of product earlier than we think in the next year or so.

THE COURT: Counsel, do you have any questions for this witness based on the questions I put to him?

MR. MEIER: Not for the government, your Honor. Markus Meier.

MR. RUDOWITZ: Not for Mr. Shkreli, your Honor.

THE COURT: You may step down.

(Witness excused)

THE COURT: Counsel, why don't we take a five-minute recess, and then we'll resume with the next witness.

(Recess)

THE COURT: Counsel, you may call your next witness.

MR. MEIER: Thank you, your Honor. Markus Meier, FTC.

We called our next witness an expert witness, James Bruno. And my colleague, Neal Perlman, will do the examination, but Mr. Perlman also has an administrative matter that we didn't complete this morning, if that's possible to just do that very quickly, your Honor.

THE COURT: So, Mr. Bruno, is that you standing? Why don't you come up here, and we'll get you seated while counsel address me, not leave you standing like that.

THE WITNESS: Thank you.

THE COURT: Just take a seat for a moment.

Counsel.

MR. PERLMAN: Good afternoon, your Honor. In our earlier discussion about the transcript of Jacob Matthew, I realize I neglected to formally move that transcript into evidence. That was GX 9052.

THE COURT: Received.

(Government's Exhibit 9052 received in evidence)

THE COURT: So, Mr. Bruno, if you could please stand and raise your right hand.

JAMES BRUNO,

called as a witness by the Plaintiffs,

having been duly sworn, testified as follows:

THE COURT: Please state your full name.

THE WITNESS: James Bruno.

THE COURT: And spell your last name.

THE WITNESS: B-r-u-n-o.

THE COURT: And you're about to be handed a document, which I believe is your affidavit. I'm going to ask you to look at that.

And what's the exhibit number, counsel?

MR. PERLMAN: It's 8001.

THE COURT: Excuse me one second.

And if you could turn to the last page, which I believe is page 37.

Mr. Bruno, did you authorize the placement of your signature on that last page?

THE WITNESS: Yes, I did, your Honor.

THE COURT: And before you did that, did you read this document with care?

THE WITNESS: Yes, I did, your Honor.

THE COURT: Do you swear to the truth of its contents?

THE WITNESS: Yes, I do.

THE COURT: Is there an offer of this exhibit, which I believe is Government Exhibit 8001?

MR. PERLMAN: Yes, your Honor. We move to admit Government Exhibit 8001 into evidence.

THE COURT: Other than the objections, which I may already have ruled on, is there any further objection to receipt of this document?

MR. PARKS: Your Honor, Manly Parks, for Mr. Shkreli. There is not.

THE COURT: Thank you.

GX 8001 is received.

(Government's Exhibit 8001 received in evidence)

THE COURT: Cross-examination?

MR. PERLMAN: Your Honor, if I may quickly, there is an appendix to GX 8001, which is a summary exhibit that plaintiffs' counsel prepared at the direction of Mr. Bruno. It's an API timeline. We would like to move that into evidence as well at this point.

THE COURT: Does it have a number?

MR. PERLMAN: Yes. It should be Appendix C in the binder. It's labeled GX 7001. It's the last tab in the binder.

THE COURT: So you're offering GX 7001?

MR. PERLMAN: Yes, your Honor.

THE COURT: Any objection?

MR. PARKS: Your Honor, Manly Parks again.

Not at this time, although we would reserve the right

to raise an objection during cross-examination.

THE COURT: Certainly.

MR. PARKS: Thank you.

THE COURT: Received. GX 7001 is received.

(Government's Exhibit 7001 received in evidence)

THE COURT: Cross-examination?

CROSS-EXAMINATION

BY MR. CASEY:

Q. Good afternoon, Mr. Bruno.

A. Good afternoon.

Q. My name is Manly Parks. I'm part of the team representing Mr. Shkreli in this matter. I'd like to start with your background, if I might.

You began your career as a technical service manager at NL Industries in 1973, correct?

A. That's correct.

Q. In that position, you were not responsible for contracts regarding APIs; is that correct?

A. That's correct.

Q. You also did not do any work with pyrimethamine while you were in that position at NL Industries, right?

A. That's correct.

Q. In your next position, as a project manager at Ganes Chemicals, you did not do any work with pyrimethamine, did you?

A. That's correct.

Q. In your position as a director of Sipsy Chemical, you did not do any work on supply agreements for pyrimethamine, correct?

A. That's correct.

Q. Sipsy Chemical did not have any supply agreements for pyrimethamine at that time, did it?

A. That's correct.

Q. Sipsy Chemical was in the business of manufacturing APIs, wasn't it?

A. Both APIs and intermediate pharmaceuticals.

Q. While you were at Sipsy Chemical, you were responsible for negotiating API supply agreements with various drug manufacturers, correct?

A. When you say "drug manufacturers," you're talking pharmaceutical companies?

(Continued on next page)

Q. Yes?
A. Yes.
Q. When you were at Sipsy Chemical, approximately 25 percent of the API contracts you negotiated had an exclusivity provision in them, isn't that right?
A. That's correct.
Q. During your time at Aerojet, none of the API supply agreements you worked on were for pyrimethamine, correct?
A. That's correct.
Q. About 15 to 20 percent of the API contracts you worked on at Aerojet had an exclusivity provision in them, correct?
A. That's correct.
Q. Would you agree that in the 1990s, exclusivity terms started to become increasingly common in API supply agreements?
A. I don't agree with that.
Q. Were you deposed in this matter on July 29, 2021?
A. It sounds like the right dates.
MR. PARKS: Can we take a look at page 42 of your deposition, lines 2 through 23.
Q. Actually, beginning at line 2 there is a question on this page presented to you. Did the nature of the business change at some point as it was relevant to exclusivity terms being in API's supply agreements? Your answer here in your deposition was: I think it changed more because, as you got into more of the '90s, we had more of the small emerging companies who were

developing products. So because they had less, I would say, chemistry, the company that was manufacturing it, there was a lot more work that we had to do. So the costs were higher. To the point, we needed to cover those costs when we were developing a product. They took longer to do it. SO we would try to get at least either a short-term supply or we would negotiate something to the effect of, we would get 70 percent of the business for some of the years, stuff like that. And that's what I referred to as the short-term supply agreement exclusivity agreement.

That was your testimony at your deposition, correct?

A. That's correct.

Q. Now, during your time at Vinchem, you did not have any role with regard to pyrimethamine supply, correct?

A. That's correct.

Q. During your time at Honeywell, that company did not look at becoming a supplier of pyrimethamine, did it?

A. That's correct.

Q. While you were at Honeywell, 30 to 40 percent of Honeywell's supply arrangements with branded drug companies contained exclusivity terms, correct?

A. That's correct.

Q. After Honeywell you formed CAP Consulting, correct?

A. It's Chemical and Pharmaceutical Solution.

Q. Can we call that CAP Consulting?

A. That's fine.
Q. During your time at CAP Consulting, none of the API supply agreements you assisted clients with negotiating pertained to pyrimethamine, correct?
A. That's correct.
Q. None of those clients of CAP Consulting were involved with pyrimethamine in any way, were they?
A. That's correct.
Q. Did you answer?
A. I'm sorry. That's correct.
Q. So it would be correct, wouldn't it, to say that in the course of your career you have not been professionally involved with anything to do with pyrimethamine, correct?
A. I have not worked on the pyrimethamine API.
Q. As part of your work on this engagement, you didn't do any formal survey regarding the frequency that different deal terms appear in API supply agreements, did you?
A. What you are calling a formal survey, I did not contact companies and do, I would say, a study.
Q. At your deposition you were asked whether you did any normal survey and you said you didn't, isn't that right?
A. I thought I just answered that.
Q. You agree you did not do any formal survey of the frequency of the different deal terms that appear in API supply agreements?

A. That's correct.
Q. In connection with this engagement you did not review any formal survey analyzing the frequency with which different terms or conditions appear in API supply agreements, did you?
A. That's correct.
Q. You were not aware of any such surveys, are you?
A. Not that I'm aware of.
Q. When you offer opinions about things being typical or unusual in the industry in this case, you are basing that on your personal experience and not in any kind of formal study or analysis or industry data, isn't that correct?
A. I'm basing my opinion on my 40 years in the industry, and also that I worked in negotiating contracts on both sides, both the CMO and the pharmaceutical company, and also in the meetings we will discuss various terms and conditions that the various CMOs and the various pharmaceutical companies are working with.
Q. So the answer to my question was, yes, isn't that right? You are not basing your opinion of things being typical or unusual on any kind of formal study or analysis or industry data. That's based on your personal experience only, isn't that right?
A. That's correct.
Q. Thank you.
Would you agree that from the API perspective there

are somewhere in the realm of 5,000 to 6,000 approved drugs in the United States?

A. That's correct.

Q. Over the course of your career you have worked on about 100 different API supply agreements, right?

A. That's correct.

Q. And of those 100 you were only closely involved with about 40 of them, correct?

A. That's not exactly what I was saying. When I said that I was the primary person on approximately 40, which meant I led the entire group. On the other contracts I'm just responsible for what I would refer to as the CMC section.

Q. Sir, at your deposition didn't you testify that you were only closely involved with about 40 of the 100 different API supply agreements you worked on in the course of your career?

A. And what I was discussing, who was the lead person, and I was the one in charge of doing it. So everything had to come to me, as opposed to me being part of the team.

Q. Sir, my question is, didn't you testify to the phrase closely involved with respect to only 40 of the 100?

A. I would have to see that again to make sure it was the exact word.

And I've lost the screen.

Q. If we can get the screen back in the meantime, perhaps we can take a look at your deposition of July 29, 2021 on page 51,

line 25 through page 52, line 10.

THE COURT: Is it up on your screen, sir?

THE WITNESS: No, it's not.

Q. Do you have it up there, sir?

A. No, I don't.

THE COURT: You can just read where you asked this question. Did you give this answer, counsel, if this is important to you.

MR. PARKS: It is. I would like to just go ahead and, if your Honor approves, I can walk up the page of the transcript so the witness can follow along.

A. Sure. I'm getting it back.

Q. Because I have the screen to read from.

A. You're on page 52?

Q. 51 to 52.

A. I see 52 in front of me right now.

Q. The question at the last line of page 51 to page 52: So in the course of this experience, you indicated that you have worked with approximately 100 pharmaceutical manufacturing contracts.

THE COURT: Slow down.

Q. And you've been closely involved with approximately 40, is that correct?

"A. That's correct."

Q. That was your testimony during your deposition, wasn't it?

A. That's my testimony.
Q. Of the 40 API supply agreements that you testified you were closely involved in, how many of them were backup supply agreements?
A. When you talk about a backup supplier, are you defining it as somebody who is ready to produce, or what I would refer to as a secondary supplier, somebody who has already made it, but they make it part of the market, so to speak.
Q. Either one of those. Broadly encompassing of those, how many of the 40 were in either of those situations?
A. Of the ones where you had a true secondary supplier, I would be negotiating either the primary or secondary supplier position.
Q. I'm asking for a number, sir. How many of the 40 that you were closely involved in were backup supply agreements under either definition you have just provided?
A. Under the definition that it was a secondary supplier in which somebody was already manufacturing, I would say at least 20 of those where I was the secondary supplier. I have to go back -- I would have to look at it again to count it, but I would say approximately.
Q. Are there any of the 40 that were in the other category you mentioned of a potential definition of backup supply agreement?
A. No, there were not.
Q. So 20 of the 40.

A. I was the secondary supplier.
Q. Now, let's turn to your substantive opinions in the case. Specifically let's talk about timing of market entry by Cerovene, InvaTech, and Fera.
Now, your opinion here does not address whether market entry by any of those firms with a generic competitor to Daraprim was delayed by some factor other than the availability of those firms to get API, does it?
A. I would say that that was correct.
Q. In your direct testimony there is a heading that states, and I'll read it: As a result of the RL Fine and Fukuzyu exclusive contracts, generic competitors had to use API suppliers that did not have a developed CGMP process. I want to examine the factual basis for that statement.
Would you agree that Cerovene's initial source for pyrimethamine was a company called Ipca?
A. That's correct.
Q. The Federal Government banned Ipca from importing API, didn't it?
A. That's correct.
Q. When did that happen?
A. Around 2015.
Q. That was well before Vyera supply agreements with Fukuzyu and RL Fine, wasn't it?
A. Vyera or Cerovene and InvaTech?

Q. Vyera supply agreements with Fukuzyu and RL Fine came well after the 2015 ban of Ipca by the government, correct?
A. If it was in 2016, yes.
Q. Well, was it in 2016?
A. When -- the work that I was looking at it was more Cerovene and InvaTech was looking at Fukuzyu and RL Fine. Vyera had taken an option more of what I was looking at of going in a different direction in the beginning.
Q. I am not sure I understood what you said there, but I am going to move on because we are going to get to the specific dates of those agreements.

Would you acknowledge that Vyera's supply agreements with Fukuzyu and RL Fine had nothing to do with Cerovene losing its initial source of pyrimethamine API?
A. My understanding with Vyera, they were looking at a totally independent once they realized that they thought they could not get the material from Fukuzyu or RL Fine.
Q. I am going to try my question again. Would you acknowledge that Vyera's supply agreements with Fukuzyu and RL Fine had nothing to do with Cerovene losing its initial source of pyrimethamine API in 2015 as a result of the Federal Government banning Ipca from importing API?
A. You're asking when Ipca was the initial supplier?
Q. Ipca wasn't their initial supplier, weren't they?
A. I just wanted to confirm that because I was a little

confused with the way the question was. But, yes, I would agree to that.

Q. Would you also agree that if the government had not banned Ipca from importing pyrimethamine API, Cerovene would not have had to look for a replacement source of API to replace Ipca?

A. For Cerovene, that's correct.

Q. Isn't it also true that if the government had not banned Ipca from importing pyrimethamine and Cerovene had continued to use Ipca as its pyrimethamine API supplier, the contracts that Vyera later entered into with Fukuzyu and RL Fine would not have caused any negative impact on Cerovene's primary pyrimethamine supply because Ipca would have still been around to source it.

A. If Ipca could still produce but they couldn't sell, then they would be able to still use Ipca's material for their formulation and for their approval in their submission.

Q. After the government banned Ipca from importing pyrimethamine, Cerovene next turned to Fukuzyu as a source of pyrimethamine API, correct?

A. That's correct.

Q. Cerovene never entered into a written supply agreement with Fukuzyu for pyrimethamine API, correct?

A. That's correct.

Q. Fukuzyu e-mailed Cerovene on October 5, 2016 to say that it has decided against supplying pyrimethamine, correct?

A. That's correct.

Q. And that is in GX-8011-007. I'm sorry. That's GX-3260. Let's take a look at that.

Sir, was this a document you reviewed in connection with developing your opinions in this case?

A. I just lost the screen again.

MR. PARKS: Your Honor, I have a hard copy to bring up until we get the screen back, just to keep it moving.

THE COURT: Thank you so much, counsel.

Q. I have handed you the first page of that exhibit. Do you recognize that as a document you reviewed in connection with the preparation of your opinions in this case?

A. Give me a second to finish reading it, please. Yes.

Q. In this document there is an e-mail to Manish at Cerovene.com forwarding a message from the president of Fukuzyu Pharmaceutical, correct?

A. That's correct.

Q. In that message from the president of Fukuzyu Pharmaceutical it states: On October 4, 2016, we, Fukuzyu Pharmaceutical, officially determined not to accept your request for pyrimethamine supply.

Pyrimethamine is a very old drug substance and the demand is not expected to grow substantially since its usage is limited. Therefore, after thorough consideration, we concluded not to supply this item to anyone because of low business

potential and high risk associated with the business. Thank you for understanding. Correct?

A. Correct.

Q. Then that is received, according to this e-mail, by Manish at Cerovene.com on October 5, 2016, right?

A. I don't have the -- there it is. Yes.

Q. Thank you.

We have Fukuzyu saying we are not going to supply pyrimethamine on October 4 and that's received on October 5, 2016.

The pyrimethamine supply agreement between Fukuzyu and Vyera is dated January 25, 2017, correct?

A. That's correct.

Q. So that supply agreement was not signed until nearly four months after Fukuzyu notified Cerovene that it was not going to supply Cerovene with product, isn't that correct?

A. That's correct.

Q. Now, Fukuzyu first agreed with Vyera to exclusivity with respect to pyrimethamine for human use in the United States on November 22, 2016, correct?

A. Sounds about the right time.

Q. Let's take a look at GX-1019, page 2, which we looked at earlier today, not with you, but with other witnesses.

A. I had it for a second. OK.

Q. The original e-mail in this chain is --

A. I don't have it again. Sorry. Now I got it.

Q. The original e-mail in this chain states: We got good news from Mikio in Japan overnight. Fukuzyu has accepted our agreement to provide pyrimethamine exclusively for us for human drugs. You see that?

A. It keeps blacking in and out and it's only up for a second and then it goes back out again. It's blinking on and off.

(Continued on next page)

BY MR. PARKS:

Q. Okay.

A. And it's blanking on and off.

THE COURT: I've asked for an entire new computer setup for the witness table, the witness box, and we're supposedly going to get it tomorrow morning. I apologize, on behalf of the court, for this technological failure.

(Pause)

MR. PARKS: I was just asking counsel for the FTC if they had any objection to me using a copy that had some highlighting on it. I think the answer was no objection.

MR. PERLMAN: The answer is no objection.

MR. PARKS: Thank you.

BY MR. PARKS:

Q. So, sir, my question for you is: Does this email refresh your recollection that the date that Fukuzyu first agreed with Vyera to exclusivity for pyrimethamine API was November 22nd, 2016?

A. Yes.

Q. Thank you.

MR. PARKS: Your Honor, I just realized, I've been traversing around the court without my mask. I apologize. I will try to remember, if I leave my station, to put it back on.

I'm going to hold off here. It's probably not fair to the witness to ask questions while someone is digging around

under the desk where he's seated.

THE COURT: Well, I'm going to ask Mr. Bruno, please, to just stand up and let our tech team get access to this space and see if they can deal with the problem. And then I'm going to ask our tech team to stay around for a couple of minutes while we use some more exhibits and see if this is cured.

COURT STAFF: Yes, your Honor.

THE COURT: Thanks so much.

(Pause)

THE COURT: I've taken some time off the clock here. And I apologize again, counsel, for I know how hard everyone's prepared, and to have this interference is frustrating.

There appears to be a whole setup, underneath the table where the witness stand is, that needs to be replaced. So it's not just the matter of a cable, it's not just the matter of a monitor; it's the matter of a whole system, and they're going to try to replace it really quickly, and, as I said, we'll replace it completely, everything, hopefully, before court tomorrow.

I see that the screen is flickering still, so right now we have to assume the monitor does not work other than in a way that will frustrate everyone.

COURT STAFF: Apologies, your Honor. My colleague is running to get a replacement.

THE COURT: Good, good. Thank you so much.

MR. MEIER: Your Honor --

THE COURT: Yes, counsel. What do you --

MR. MEIER: I had one matter I was going to ask the Court about for some guidance at the end, so we could at least ask about that now, if it works for, your Honor?

THE COURT: Sure.

MR. MEIER: As your Honor knows, the parties have been working very hard to work out objections, and your Honor has given us a lot of guidance along the way to help us understand the objections on documents and the objections on designations, and this is really an administrative matter to ask your Honor's preference.

Going forward, in light of all of the rulings and all of the work we've already done, do you have a preference as to whether we raise any remaining objections? Should we submit them in writing or address them, as we did this morning, with Mr. Perlman before we start for the day? Is there a preference for the future? I think we've worked out an awful lot, but we're trying to figure out whether we should continue to submit writings to your Honor with objections about deposition designations and objections to exhibits, or whether we just take it case by case --

THE COURT: I think we take it case by case during the trial day.

MR. MEIER: All right. Thank you.

THE COURT: Mr. Bruno, I hate to keep you standing.

Did you want to take a seat back there?

THE WITNESS: If you don't mind.

(Pause)

MR. POLLACK: Your Honor, may I be briefly excused?

THE COURT: Sure, sure, yes, counsel, whenever you need to take a break. Obviously, if examining counsel or principal counsel for a witness needs a break, I'll take a break for everyone, but, otherwise, feel free go in and out.

MR. PARKS: Thank you, your Honor.

(Pause)

THE COURT: With my great thanks to our technical team here, I think we've reached the conclusion that there is no quick fix this afternoon, it's going to require an overhaul; and so, counsel, can you manage an examination of the witness without the screen?

MR. PARKS: I believe I can, your Honor. I think I have hard copies, to the extent I need to use any, and I can bring them up. And if I am wrong about that, I will stand corrected as we go and I will have to skip over that portion, I suppose, but I do believe I have hard copies of anything I need.

THE COURT: Good. They might have just fixed it, but there are no guarantees, is the point. We're in unknown territory.

We start at 9:30 in the morning, so you will be able to replace it before then?

COURT STAFF: Yes, your Honor.

THE COURT: Good. Thank you, thank you.

Mr. Bruno, if you could come on up here, and perhaps the screen will work and perhaps it won't.

I'm going to ask you, Mr. Bruno, to move that mic back into place so you'll be speaking into it, sort of under your chin, not too close. Great.

Counsel, thank you, again, for your patience. You may resume.

MR. PARKS: Thank you, your Honor.

BY MR. PARKS:

Q. Mr. Bruno, you understand you're still under oath, correct?

A. That's correct.

Q. Let's just recap a moment since we've had this little break.

We can agree that Vyera had nothing to do with Cerovene losing its original API source, Ipca, right?

A. That's correct.

Q. That happened as a result of the federal government, right?

A. Correct.

Q. The supply agreement between Vyera and Fukuzyu was dated almost four months after Fukuzyu declined to supply Cerovene with pyrimethamine API, correct?

A. Correct.
Q. Fukuzyu first agreed to exclusivity on November 22nd, 2016, which was nearly two months after Fukuzyu declined to supply API to Cerovene, correct?
A. Correct.
Q. We can agree, can't we, that an agreement dated January of 2017 could not possibly have been the reason that Fukuzyu declined to supply a pyrimethamine API to Cerovene in October of 2016, right?
A. I'm not sure I can agree with you completely. Agreements like this take time to negotiate, so I don't -- you'd have to go back and look at what was going on internally, and were they taking a longer period of time in that respect. It could have been coincidental. It also could have been that they were under-the-gun negotiations and that's where they were when they made the decision.
Q. You don't have any evidence to suggest that -- withdrawn.

You didn't identify any evidence in your expert reports or your direct testimony in this case that Vyera insisted that Fukuzyu decline to supply Cerovene with API on October 4th, 5th, 2016, do you?
A. I didn't see that.
Q. Thank you.

Now, the next API supplier that Cerovene turned to after Fukuzyu was RL Fine, correct?

A. Correct.
Q. Cerovene entered into an exclusive supply agreement with RL Fine on November 16, 2016, correct?
A. That's correct.
Q. And that was actually before Fukuzyu and Vyera first reached agreement on exclusivity on November 22nd, 2016, wasn't it?
A. Would you repeat that?
Q. Sure.

The date that RL Fine and Cerovene entered into an exclusive supply agreement, November 16, 2016, was actually before Fukuzyu and Vyera first reached agreement on exclusivity, which was November 22nd, 2016, we saw from an email a few moments ago, right?
A. Okay, yes.
Q. Now, Cerovene has taken the position that its exclusive supply agreement with RL Fine helped it to maintain high quality and avoid drug shortages and protect revenues, hasn't it?
A. That's correct.
Q. And you recognize that those are, in fact, benefits that can come from an exclusive supply agreement, don't you?
A. Those would be benefits, yes.
Q. In any event, we can agree that -- withdrawn.

Turning back to the exclusive supply agreement between

Cerovene and RL Fine, RL Fine ended that supply relationship with Cerovene on November 30, 2017, correct?

A. Correct.

Q. And we know that because if we look at the affidavit of Mr. Sha, which is GX 8011 --

MR. PARKS: And I believe this has already been entered into evidence today. Am I right about that? 8001?

Q. Sir, are you familiar with the direct testimony of Mr. Sha?

A. I remember reviewing it earlier on.

Q. And you cite that affidavit in your direct testimony in this case, don't you?

A. Yes.

Q. So you reviewed it, right?

A. Yes.

Q. And if we look at paragraph 39 of Mr. Sha's affidavit --

MR. PARKS: I'm going to walk this up.

A. I have it in front of me now.

Q. Oh, you have it in front of you? Great.

Mr. Sha testified under oath that: On or around November 30, 2017, he traveled to India and met with RL Fine executives to finalize the commercial supply of pyrimethamine that Cerovene was expecting from RL Fine. Mr. Mathew, the same senior executive at RL Fine with whom I met at Cerovene's offices earlier in 2017, told me that RL Fine would no longer supply API to Cerovene, right?

A. Correct.
Q. So we know that RL Fine communicated that message on November 30, 2017, from Mr. Sha's affidavit. We also know that the supply agreement between RL Fine and Vyera was dated December 27th, 2017, correct?
A. Correct.
Q. So RL Fine ended its supply relationship with Cerovene a full month before RL Fine entered into the supply agreement with Vyera, correct?
A. Correct.
Q. We can agree, can't we, based on the simple linear time principles, that an exclusivity provision in an agreement that did not come into existence until December 27, 2017, could not possibly have prevented RL Fine from supplying Cerovene with pyrimethamine in November of 2017? Correct?
A. Again, I have no evidence to it, but because it's a month apart, I didn't read a document that said that, so I couldn't -- I can't necessarily agree with you. I didn't see anything, I can agree to that, but, again, there could have been negotiations going on, and they could have been close to the end and that would have had the two dates coincide like that.
Q. But even in that scenario, the agreement wouldn't have been the preventative factor, right, because the agreement didn't exist yet, correct?

A. But, again, if the agreement was under -- if they thought they were close to an agreement, is what I'm trying to say, then that could have triggered the two events.

Q. You have just told us you saw no evidence indicating that, right?

A. That's my point.

Q. Thank you.

Speaking of this timing issue, I would like to ask you about Appendix C to your affidavit that was submitted as part of your direct testimony in this case. Let's take a look at that. That's GX 7001. And we have the redacted public version up on the screen here, I believe.

MR. PARKS: Now, this has been moved into evidence, and, your Honor, you'll recall that I reserved objections on this and I want to now look into this document a bit with this witness.

Q. What, generally speaking, are we looking at here on the screen?

A. You're looking at an API development timeline for, I would say, the three main companies, other than Vyera.

Q. Now, who prepared this document? Or this exhibit?

A. It was prepared by the FTC. I gave them the information, and they actually did the document. They're more attuned to be able do these things than I am. And I just lost the screen.

I got it back.

Q. Now, if we go to the bottom of page 2 of this document, in the very bottom of that page, there is an italicized sentence that states: The timeline was prepared by attorneys and paralegals at the FTC, subject to my review and approval?
A. Correct.
Q. My question for you, sir, is: Did you review it, and did you approve it?
A. Yes, I did.
Q. And this was created for use as a visual aid, right?
A. That's correct.
Q. Now, if we look back to the timeline itself — I want to focus on the bar that says "Cerovene" at the left — there is an entry in that bar that says: Item 5 RL Fine ends relationship December 2017.

Do you see that?

A. Yes, I do.
Q. Do you see directly above that there is an entry that says: RL Fine December 2017? Do you see that?
A. That's correct.
Q. And that's to indicate when Vyera's exclusive contract with RL Fine happened, right?
A. That's correct.
Q. Now, this document we're looking at here, your demonstrative, indicates that RL Fine's entry into an exclusive agreement with Vyera was simultaneous with when RL Fine ended

its supplier relationship with Cerovene, doesn't it?
A. That's correct.
Q. But the fact is, those events were not simultaneous, were they?
A. The RL Fine agreement was December 2017 and the ending the relationship was December 2017.
Q. Sir, we just looked at an email from Mr. Sha, I believe, indicating that he traveled to RL Fine in India and had the discussion with them on November 30th, 2017. That was paragraph 39 of the Sha affidavit.

Do you remember that from a few moments ago?

A. Yes, I do.
Q. So December 2017, on your exhibit, is wrong, isn't it?
A. They had the visit on November 30th. I wouldn't consider this to be necessarily wrong, because the agreement was signed on or about, or it was preparing to be signed, but it was effective in December, and November 30th is the end of November, it's the end of the month going into December.
Q. So November 30th is actually December; is that your testimony?
A. No, that is not my testimony. All I'm saying is that it's very possible -- as I'm trying to say, the dates almost coincide exactly, and to be notified they could have been prepared to sign the agreement, and from that point on, it would have been, one event triggered the other event.

Q. You have no information, you've already told us, that one event triggered the other event, right?
A. Yes.
Q. Okay.
But this exhibit makes it look like these two things were simultaneous when, in fact, there was a month between them, right?
A. You're assuming that December is the last day of the month and November was the last day of the month.
Q. Sir, I'm not assuming anything. We've already gone through these documents, and you've testified that the date of the RL Fine-Vyera agreement was December 27th, 2017, and we know from Mr. Sha's affidavit that the date that RL Fine declined to supply pyrimethamine was November 30th, 2017, and, by my count, November 30th is almost a month from December 27th, right?
A. Correct.
Q. So your document, that makes these events look simultaneous, is inaccurate, isn't it?
A. Again, I'm saying that while these documents -- and I consider them to be accurate in the sense that it ended on -- if you want to say the November 30th should have been the date instead of December, ending the relationship, I will give you that. But I would also -- based on looking at the timelines and the approximation of the timelines, one event preceded the other, where normally I would have said it would have been the

other way around.

Q. Okay.

MR. PARKS: I'm going to move to strike "the normally I would have said it would be the other way around" because that's not an expert opinion that's been in any of his reports or in his direct exam, and I don't know that he has any basis to talk about how frequently or infrequently these events occur and how they coincide with one another, your Honor.

THE COURT: Overruled.

MR. PARKS: Your Honor, I would also raise an objection to this demonstrative as inaccurate and move that it be stricken.

THE COURT: That's denied. But I get your point, that the December 2017 should have said November, and that the contract with Vyera wasn't executed until December 27th.

So I get that point, counsel, so I thank you.

MR. PARKS: Okay. We will move on. Thank you, your Honor.

BY MR. PARKS:

Q. Let's take a look at -- let's discuss Vyera's negotiating leverage and your testimony about missing risk management terms in that agreement between Vyera and RL Fine.

Your opinion is that the Fukuzyu contract -- I'm sorry, let's talk about the Fukuzyu contract first.

Your opinion is that the Fukuzyu contract — that is,

Fukuzyu and Vyera — did not mitigate supply risk, correct?
A. That's correct.
Q. And in your direct testimony, you identified various provisions that you said would have reduced supply risk for Vyera, right?
A. That's correct.
Q. You discussed the concept of a requirements provision, right?
A. That's correct.
Q. And you discussed the concept of a capacity reservation clause, right?
A. That's correct.
Q. Sir, Fukuzyu would have had to agree to the inclusion of those provisions in the agreement with Vyera before they could go into the agreement, right?
A. If it's not written in the agreement, then it's not part of the agreement.
Q. But in order for the parties to reach agreement, both parties have to agree to put those terms in the agreement, don't they?
A. They need to have those terms in the agreement, yes.
Q. You don't identify any evidence in your reports or in your direct testimony, that Fukuzyu actually was willing to agree to either of those types of provisions in this agreement with Vyera, do you?

A. Unless it's written in the agreement -- and, again, these are just several points, so they might have covered one, but I was just trying to give examples of different ways of which this is handled.

Q. Sir, my question was: You don't have any evidence that Fukuzyu actually offered to agree to those provisions you said should have been in this agreement? You don't have any such evidence, do you?

A. Again, unless they're in the agreement, then it's not part of the agreement.

Q. I'm not asking what's in the agreement. I'm asking whether Fukuzyu offered to put them in the agreement.

A. I saw no evidence that they either agreed to or didn't agree to.

Q. You don't know whether Fukuzyu offered to put in those terms that you say should have been in there to mitigate supply risk or not, do you?

A. I do not.

Q. And if Fukuzyu said no to a request to add those types of supply terms, you certainly can't fault Vyera for that, can you?

A. Again, if Vyera is negotiating the contract, and if I'm negotiating the contract and these are my, I would say, important points, then it's up to you to get them in the contract.

Q. To quote the great philosopher Mick Jagger, you can't always get what you want, right?
A. But this is part of negotiation, and if this is your number one product that's your greatest part of your revenues, you need to pick the ones that are most important, and one of the most important ones for Vyera is to have a constant and continuous supply of API, and that's mitigating the risk, and what did you do to mitigate the risk?
Q. But we can agree, either way, that Vyera couldn't just dictate to Fukuzyu what Fukuzyu was going to agree to, could it?
A. It's part of the negotiations of the contract.
Q. So the answer is, they couldn't just dictate to Fukuzyu, could they?
A. But they could have put their terms in place that they wanted and found ways to control their supply.
Q. I take it we're in agreement that Vyera could not dictate to Fukuzyu what would go in the contract?
A. I don't agree with you completely. If I'm the one purchasing it, then it's up to you to negotiate it, and, in that respect, you should be able to dictate some of the terms or come to a compromise between the terms.
Q. As between Fukuzyu and Vyera, Fukuzyu had more bargaining power in the negotiation over the terms of the API supply agreement, didn't it?

A. I don't agree that either side has greater bargaining powers. At least in my experience of contracts, we don't approach the contract from a "who's got the upper hand," so to speak. This is supposed to be a mutually agreeable event that you've worked on in order to do it. So each side is going to have to give a little.

Q. So bargaining power doesn't matter in pharmaceutical API supply agreements; is that your testimony?

A. I didn't say that.

Q. Okay.

A. I said it's part of the negotiations.

Q. Now, sir, you stated in your direct testimony that Vyera's pyrimethamine purchases from Fukuzyu were small when compared to the amount of pyrimethamine purchased by GSK from Fukuzyu, right?

A. That's correct.

Q. In your direct testimony, you pointed out that Vyera faced a risk that Fukuzyu might supply its larger customer, GSK, first before Vyera, and that presented a risk to Vyera that its supply of pyrimethamine might be interrupted, correct?

A. That's why I needed to have some kind of control over being able to continue my supply and guarantee I could get it.

Q. You would acknowledge, as a result of the relatively small amount of API being purchased by Vyera, that it was not in a particularly strong bargaining position with respect to

Fukuzyu, wouldn't you?
A. When you're talking about the bargaining power, yes, they were a small potential client of Fukuzyu -- of Fukuzyu, so they didn't have the buying power, for sure, that the GSK would have had.
Q. In your direct testimony affidavit, you discuss GSK's API supply agreement with Fukuzyu, don't you?
A. Yes, I do.
Q. And you note that GSK's supply agreement with Fukuzyu contains both a requirements provision and a capacity reservation clause, right?
A. That's correct.
Q. Would you agree that GSK purchases large quantities of pyrimethamine from Fukuzyu?
A. That's correct.
Q. Would you agree that a larger, more well-known company, like GSK, is able to use its size as leverage to secure better treatment from an API supplier as compared to a small buyer, like Vyera?
A. I would expect that.
Q. In fact, in your direct testimony, you wrote, "In my experience, an API supplier is more likely to supply its larger customer over a smaller one, particularly a well-known company like GSK, that could sponsor additional business on other APIs," right?

A. This is why I emphasized in the need for risk mitigation for the supply of the API.

Q. And in your critique of Vyera for failing to get deal terms from Fukuzyu like those GSK was able to secure, you don't mention the massive difference in negotiating leverage between Vyera and GSK, do you?

A. I was looking at the point that Vyera needed to have in place some kind of mechanism to guarantee that it would not have an interrupted supply of API; it had, in effect, no part with regards to the bargaining, it should have been up to Vyera, who's -- again, it's their primary product. They should have been responsible for developing some mechanism that both Fukuzyu and they could agree to.

Q. Back to my question: In your critique of Vyera for failing to get deal terms from Fukuzyu like those GSK received, you don't mention the massive difference in negotiating leverage between Vyera and GSK, do you?

A. I had already mentioned it into the document, so I already documented this was one of the issues that were there. Again, Vyera has to find a way — and I listed other ways — to mitigate the risk of supply.

Q. In your direct testimony, you note that the requirements in capacity reservation provisions in GSK's supply agreement with Fukuzyu require Fukuzyu — and I'm quoting now — to ensure that it meets GSK's requirements first, unquote, direct testimony

paragraph 23.

Can we agree that it would not have been possible for Fukuzyu to also make such a commitment to Vyera because that commitment to Vyera would be inconsistent with its preexisting commitment to GSK?

A. I think two things, when I look at it:

For one, if that is the question, because GSK was supplying them with forecasts, they knew how much they needed to supply for GSK, so in their production planning, they could have just equally had -- made sure that there was enough issue there for that, or, again, Vyera could have used another method to secure the supply of the raw material, like buying extra material and some of the other techniques that I also mentioned in my report.

Q. Sir, if Fukuzyu has promised GSK that GSK will be first, as you've told us in your direct testimony, Fukuzyu can't also promise Vyera that Vyera will be first, can it?

A. I'm not saying that one would be first and one would be second. I think the point is, if you know I need a hundred kilos for one and I've guaranteed them that 100, I should be able to, again, go into my planning -- and that's what a CMO will do, and they'll probably make additional quantity.

And I worked for a number of CMOs. This is what we did all the time. We negotiated -- or we planned for those upswings; could be 20, 30, 40 percent. So I could have in my

planning made sure that I had it.

So I don't consider it to be inconsistent because they were guaranteeing one versus the other. It's a question of planning, and it's a question of finding ways to mitigate the risk.

Q. Sir, there can only be one first, right?

A. I'm not disagreeing, first versus second. What I'm saying is, with your planning, if I need a hundred, I make 120; if I need 200, I make 250. There's nothing unusual about that in the CMO. We never make the exact amount of material.

Q. As you've told us, under the agreement between GSK and Fukuzyu, GSK was first, right?

MR. PERLMAN: Objection, your Honor. I'm not sure that this is in Mr. Bruno's report. It's certainly not in paragraph 23.

So would you direct us to the right paragraph?

MR. PARKS: Sure. I will freely admit my own notes might be wrong, but that is what my notes tell me is in paragraph 23.

THE COURT: Yes, I think paragraph 23 may be a miscite, if you mean paragraph 23 of the direct testimony.

MR. PARKS: Yes, it appears to be a miscite. And I will see if I can correct the record on that at my first opportunity.

THE COURT: Okay.

MR. PARKS: But I have it in quotes in my notes, which helps me believe I didn't invent it out of thin air.

THE COURT: Okay, good.

You know, we have perhaps two minutes to go until 5:00 o'clock, but shall we say this is a good time for a break, for the day? Or, counsel, did you have a question or two you wanted to follow through on this topic?

MR. PARKS: I have a pretty limited amount. We can resume tomorrow morning, but I probably have no more than ten minutes, possibly even only five, to complete my exam of this witness. So it's the Court's preference. I'm happy to stop, here, or go for a couple questions, or happy to go for five or ten more minutes and finish.

THE COURT: No, we're going to stop promptly at 5:00. So the question was a minute or two more.

MR. PARKS: Okay, this is a good stopping point. I'm actually at the end of a section and ready to move into another.

THE COURT: Okay, good.

Mr. Bruno, you can step down. Thank you.

(Witness temporarily excused)

(Pause)

THE COURT: Counsel, I'm going to confirm this in the morning because I have some backup record keepers here, but it looks to me like the plaintiff has used three hours and

fourteen minutes and the defendant one hour and forty-seven minutes, so it should be roughly that amount, and I'll confirm in the morning.

We're going to start again at 9:30. I think we're a little bit behind where we expected to be today, if I remember our witness list.

Expectations?

MR. MEIER: That's correct, your Honor.

THE COURT: Okay, good.

So thank you for sending an email last night with your expectations for tomorrow, but I am assuming that we're going to complete the witnesses you plan for today first and then go for the witnesses you would plan to do tomorrow; is that right?

MR. MEIER: That is correct, your Honor.

THE COURT: Okay.

If you change your minds, that's just fine, too. I know you have a lot to juggle in terms of witness plans, and you'll accommodate each other's needs and your witnesses' needs, but just shoot us an email — again, that's very kind — to let us know what you expect.

I think that's it. Have a good night, everyone. And I'll see you at 9:30, hopefully, with new equipment at the witness stand.

(Adjourned to December 15, 2021 at 9:30 a.m.)

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INDEX OF EXAMINATION

GOVERNMENT EXHIBITS

DEFENDANT EXHIBITS